



Santen

# Eyeing Further Specialization

SANTEN PHARMACEUTICAL CO., LTD. Annual Report 2013  
Year Ended March 31, 2013

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### NOTE CONCERNING GRAPHS

Graphs in this annual report are based on fiscal years ended March 31, if no note is specified.

### NOTE CONCERNING DATA

Some information in this annual report is based on IMS data (JPM).  
Source: ©2013 IMS Health  
Santen analysis is based on IMS-JPM data from April 2008 to March 2013.  
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### CAUTION CONCERNING FORWARD-LOOKING STATEMENTS

This annual report contains forward-looking statements regarding the Company's plans, outlook, strategies and results for the future. All forward-looking statements are based on judgments derived from the information available to the Company at the time of publication. Certain risks and uncertainties could cause the Company's actual results to differ materially from any projections presented in this report. These risks and uncertainties include, but are not limited to, the economic circumstances surrounding the Company's businesses, competitive pressures, changes in related laws and regulations, status of product development programs and changes in exchange rates.



## Santen's Values

Core Value

# *Tenki ni sanyo suru*<sup>1</sup>

We think carefully about what is essential,  
decide clearly what we should do, and act quickly.

## Mission Statement

By focusing our efforts on ophthalmology and related areas, we develop scientific knowledge and organizational capabilities which are unique and original to Santen. We use our unique capabilities to contribute to patients and their loved ones, and consequently to society.

1. Santen's original interpretation of a passage from chapter 22 of Zhongyong (The Doctrine of the Mean) by Confucius, meaning "exploring the secrets and mechanisms of nature in order to contribute to people's health."

1890

Santen's Values embody what the Company has continued to recognize as important since its foundation in 1890. Based on Santen's Values—the essence of which is "*tenki ni sanyo suru*"—we have put in place a virtuous cycle of creation and innovation while contributing to the protection and improvement of eyesight and health as a specialty company in the ophthalmic and anti-rheumatic fields. Building on the scientific knowledge and organizational capabilities that Santen has nurtured for over 120 years, the Company will continue to contribute to society, working primarily for the benefit of patients and their loved ones.

# Santen's Strengths and Strategic Vision

## Business Domains

We channel management resources into the specialized fields of ophthalmology and anti-rheumatics to create innovative drugs sought by the medical community and provide high-quality medical information based on market needs. In this way, we have enhanced Santen's market reputation.



Further Information

P.12 Feature

P.24 Review of Operations

## Prescription Ophthalmic Pharmaceuticals (Sales Composition)

# 83.1 %

Position in  
Japanese Market

# No.1<sup>1</sup> (Market Share 35.3%)

The number of ophthalmologists in Japan  
is currently around 13,000.  
Santen's approximately 400-strong medical representative (MR) workforce  
strives diligently to call on virtually every one of Japan's ophthalmologists  
to provide detailed pharmaceutical information.

Prescription  
Anti-Rheumatic  
Pharmaceuticals

# 8.3%

Position in  
Japanese Market

Disease-Modifying  
Anti-Rheumatic Drugs<sup>2</sup>

# No.2<sup>1</sup>

(Market Share 39.7%)

Over-the-Counter  
Pharmaceuticals

# 5.4%

Position in Japanese Market

# No.2<sup>3</sup>

(Market Share 19.1%)

Medical Devices 1.9%

Others 1.3%

Fiscal 2012 Net Sales

# ¥119.1 billion

2011

## Fiscal 2011-2013 Medium-Term Management Plan

2013

Notes: 1. Market share and market position in Japan for the fiscal year ended March 31, 2013.  
The share and position for anti-rheumatic pharmaceuticals represent those in the DMARDs segment.  
Source: Santen analysis based on IMS-JPM data.

2. A class of medicines that are used not only to alleviate symptoms but also to treat the causes of disease. The anti-rheumatic effect works by calming inflammation through the correction of immune abnormalities, which are considered a cause of RA.

3. Market share and market position in the Japanese OTC eye drop market for the fiscal year ended March 31, 2013. Source: Santen Pharmaceutical Co., Ltd.

Countries in  
Which Products Are Sold

# Over **50** countries



Annual Production Capacity of  
Ophthalmic Solutions

**Approx. 300 million bottles**

## Global Business Expansion

Santen maintains 13 bases spread across 10 countries, and its products are sold in over 50 countries worldwide. Santen produces around 300 million bottles<sup>4</sup> of ophthalmic solutions each year at four plants—in Noto, Shiga, Suzhou (China) and Tampere (Finland). That makes us a world leader in the production of ophthalmic solutions.

4. On a 5 mL bottle conversion basis



Further Information

P.30 Overseas Operations

## Our Long-Term Strategic Vision for 2020

2020

# A Specialized Pharmaceutical Company with a Global Presence

## Strategic Vision

Santen has set forth the goal of becoming a specialized pharmaceutical company with a global presence as its long-term strategic vision for 2020. Santen is focusing its collective power to execute its Fiscal 2011–2013 Medium-Term Management Plan as the first step of its long-term strategic vision.



Further Information

P.6 President and CEO's Message

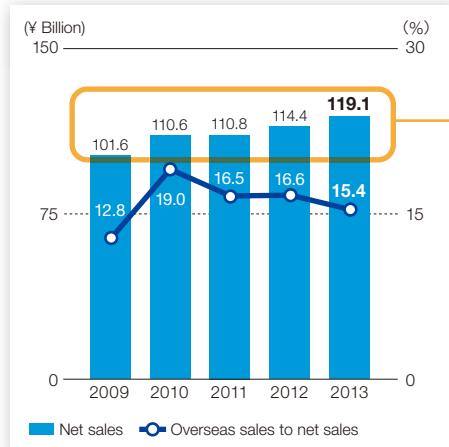
# Consolidated Financial Highlights

Santen Pharmaceutical Co., Ltd. and Subsidiaries  
Years ended March 31, 2013, 2012, 2011, 2010 and 2009

	Millions of yen					Thousands of U.S. dollars	Change
	2009	2010	2011	2012	2013	2013	2013/2012
<b>For the year:</b>							
Net sales	¥ 101,619	¥ 110,594	¥ 110,812	¥ 114,416	¥ 119,066	\$ 1,265,987	4.1%
Operating income	15,494	29,640	30,739	26,732	24,681	262,427	(7.7)
Net income	10,123	18,723	21,333	17,161	16,521	175,661	(3.7)
Comprehensive income	4,896	18,826	19,797	16,966	21,729	231,036	28.1
R&D expenditures	18,458	14,123	13,221	17,225	16,720	177,777	(2.9)
Capital expenditures	2,953	1,315	1,651	3,281	3,609	38,368	10.0
Depreciation and amortization	4,210	3,421	2,976	2,949	3,291	34,991	11.6
<b>At year-end:</b>							
Total assets	¥ 151,012	¥ 166,878	¥ 184,801	¥ 198,801	¥ 199,641	\$ 2,122,707	0.4%
Long-term debt	154	75	152	179	145	1,538	(19.0)
Equity	125,181	137,343	156,099	164,514	164,808	1,752,346	0.2
<b>Per share data</b> (yen and U.S. dollars):							
Net income – basic	¥ 119.08	¥ 220.10	¥ 249.71	¥ 196.96	¥ 195.81	\$ 2.08	(0.6)%
Net income – diluted	118.97	219.85	249.42	196.76	195.51	2.08	(0.6)
Equity	1,472.32	1,614.08	1,793.15	1,887.81	1,998.44	21.25	5.9
Cash dividends, applicable to the period	80.00	80.00	90.00	100.00	100.00	1.06	0.0
<b>Other financial data:</b>							
Operating income margin (%)	15.2	26.8	27.7	23.4	20.7		
Overseas sales to net sales (%)	12.8	19.0	16.5	16.6	15.4		
R&D expenditures to net sales (%)	18.2	12.8	11.9	15.1	14.0		
Return on equity (ROE) (%)	8.0	14.3	14.5	10.7	10.0		
Dividend on equity (DOE) (%)	5.4	5.2	5.3	5.4	5.1		
Number of employees	2,690	2,756	2,867	3,053	3,050		

Notes: 1. U.S. dollar amounts have been translated from yen, solely for the convenience of the reader, at the rate of ¥94.05 to U.S.\$1.00, the exchange rate prevailing on March 31, 2013.  
 2. See Notes 2, 15) and 13 of Notes to Consolidated Financial Statements in respect of per share data.  
 3. Figures in parentheses indicate a decrease.  
 4. Equity comprises shareholders' equity and accumulated other comprehensive income.

Net Sales and Overseas Sales to Net Sales



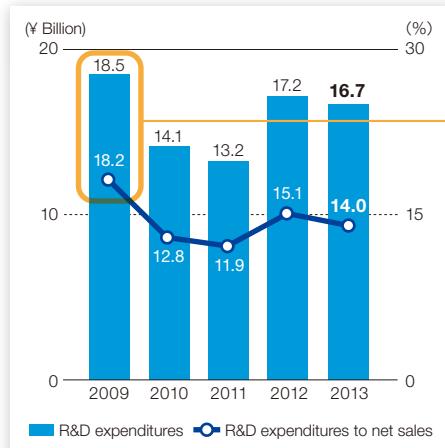
Despite the impact of drug price revisions in Japan every two years, net sales have grown stably, driven mainly by steady growth of new products.

Operating Income and Operating Income Margin



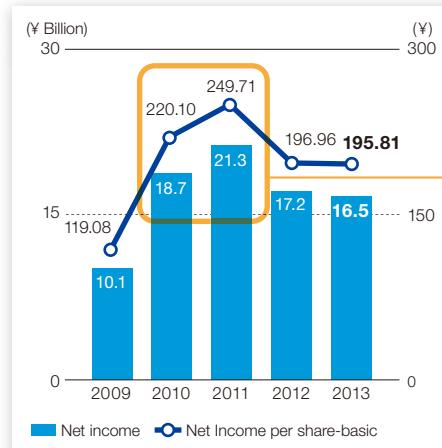
Operating income increased due to the recording in net sales of one-time payments included from product and technology licensing agreements with U.S.-based companies Merck & Co., Inc. and Bausch & Lomb Inc. Another factor was the absence of a one-time payment to U.S.-based MacuSight, Inc. in the previous fiscal year.

### R&D Expenditures and R&D Expenditures to Net Sales



This was mainly the result of recording US\$50 million as a one-time payment following the conclusion of an agreement for the acquisition of global rights for development and marketing of DE-109 (sirolimus) with MacuSight in May 2008.

### Net Income and Net Income per Share-Basic



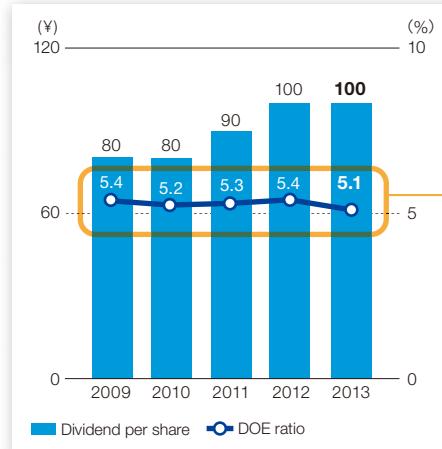
Santen posted record net income for the second straight year mainly on the back of growth of tafluprost, a glaucoma and ocular hypertension treatment launched in Japan in December 2008.

### Equity and ROE



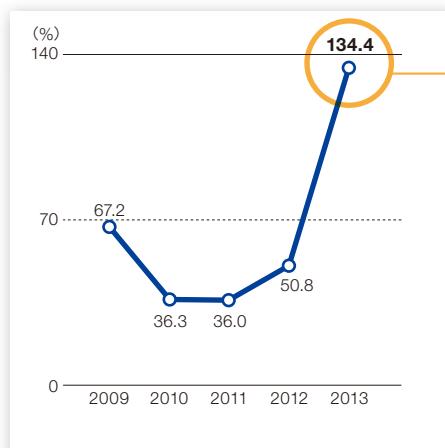
ROE dropped to approximately 2 percentage points in the fiscal year ended March 31, 2009 due to a lower profit ratio resulting from a payment for licensing in a product from MacuSight. However, ROE rose to approximately 6 percentage points in the fiscal year ended March 31, 2010 due to one-time payments included in revenues from licensing out products.

### Dividend per Share and DOE



DOE has remained above the 5% target, the result of implementing a dividend policy aligned with profit growth.

### Total Return Ratio<sup>5</sup>



Santen repurchased its own shares at a total cost of ¥13.7 billion in August 2012. In November 2012, it cancelled almost of treasury shares, equivalent to 5.67% of the total number of outstanding shares before the cancellation.



#### Further Information

[P.42 Report and Analysis of Operating Results and Financial Condition](#)

[P.46 Risk Related to Our Business](#)

[P.48 Eleven-year Summary of Selected Financial Data](#)

5. The sum of dividends and the cost of share buybacks divided by net income

## President and CEO's Message

Santen is determined to meet the challenge outlined in its long-term strategic vision for 2020 of becoming a specialized pharmaceutical company with a global presence.

In line with Santen's Values, we fulfill our social responsibilities by providing innovative products and services that satisfy unmet medical needs. As we endeavor to accomplish our goals, we kindly ask for the continued support of all our stakeholders.

September 2013



A. Kurokawa

Akira Kurokawa  
President and Chief Executive Officer

## Fiscal 2012 Overview

**We posted record net sales.**

**I believe that we made steady progress toward realizing our long-term strategic vision, even though earnings declined temporarily as we continued to invest aggressively for future growth.**

During fiscal 2012, the fiscal year ended March 31, 2013, Santen made aggressive up-front investments for medium-to long-term growth, with a particular focus on investments in R&D and strengthening our operating platform. Net sales grew steadily in Japan and overseas, rising 4.1% year on year to ¥119.1 billion. However, operating income fell 7.7% to ¥24.7 billion and net income fell 3.7% to ¥16.5 billion mainly because of National Health Insurance (NHI) drug price revisions in Japan and higher costs due to the acquisition of European subsidiary Santen S.A.S. (formerly Novagali Pharma S.A.S.).

In our prescription ophthalmics business, we saw steady sales growth for a number of new products, including our glaucoma and ocular hypertension treatment tafluprost (sold as *Tapros* in Japan), as well as our combination ophthalmic solution *Cosopt* for glaucoma and ocular hypertension, and our dry eye treatment *Diquas* (diquafosol sodium). Also, due to growth in other mainstay products, we were therefore able to absorb the impact of NHI drug price revisions and report a solid increase in sales. We launched *EYLEA* (afibercept [genetical recombination]) for wet age-related macular degeneration (wet AMD) in Japan in November 2012 and penetrated the market faster than forecasted. We view this market penetration by *EYLEA* as a foothold for contributing to treatments in the field of retinal disorders, where there are high unmet medical needs, as we aim to establish a solid market position. Tafluprost is the growth driver in our overseas business and is now available in over 60 countries worldwide<sup>1</sup>, including sales by U.S.-based Merck & Co., Inc. in the U.S., Western Europe, and Latin America.

In R&D, we created the position of Chief Scientific Officer (CSO) in April 2013 to strengthen our global R&D strategy

function and appointed to this role Dr. Naveed Shams, the CEO of U.S. subsidiary Santen Inc. With this new R&D system, we are working to improve productivity and aim for an organization capable of generating competitive new pharmaceuticals based on the therapeutic needs of patients around the world.

In order to achieve our long-term strategic vision, we are working across the organization to drive our business forward, by harnessing our proprietary knowledge and organizational capabilities in the ophthalmic and anti-rheumatic fields.

1. As of August 6, 2013

## Enhancing Shareholder Returns

Santen has positioned the return of profits to shareholders as a key management priority. In order to ensure the continuous and stable payment of dividends to shareholders, the Company has adopted the dividend on equity (DOE) ratio, which multiplies the dividend payout ratio by ROE, as an indicator for total shareholder returns.

For fiscal 2012, we paid a full-year dividend of ¥100 per share, the same amount as for the previous fiscal year. This resulted in a DOE of 5.1%, which means DOE has now exceeded 5% for six years in a row. In fiscal 2013, we are committed to the stable return of profits to shareholders and a DOE of 5% or more. At the same time, we will continue to retain funds primarily for R&D investments, while adopting a flexible stance that includes the acquisition of treasury stock. In fiscal 2012, we repurchased our own shares at a total cost of approximately ¥13.7 billion and cancelled 4,938,500 shares of treasury stock in order to enhance capital efficiency and improve shareholder returns.

### Fiscal 2011-2013 Medium-Term Management Plan

#### Strategic Objectives

1. Promote globally oriented research and development.
2. Obtain high domestic market share and achieve growth through the promotion of new products and implementation of marketing strategies.
3. Accelerate growth in both Asia and Europe by reinforcing marketing platforms.
4. Establish a global product supply system with our existing four plants<sup>2</sup>, which enable us to meet emerging market needs.
5. Develop talents and organizational capabilities to promote "creation and innovation" on a global level.

2. Four plants: Noto and Shiga Product Supply Center\* (both in Japan); Suzhou (China); and Tampere (Finland)

\*Name changed from Shiga Plant on July 1, 2013

## Research and Development

**By fostering closer links between bases in Japan, the U.S. and Europe, we will work to expedite development, placing emphasis on maximizing the cost-benefits of investments and addressing unmet needs.**

For R&D, all Santen group companies are working together to achieve the long-term strategic vision for 2020 based on a strategic objective of “promoting globally oriented research and development.”

For research, we have introduced project management tools; started up the “KANAME” project aimed at facilitating rapid problem solving and promoting seamless development between Japan, the U.S. and Europe; and are maximizing the cost-benefits from our investments.

For clinical development, we have expanded functions to establish POC<sup>1</sup> at the early stages of clinical development, with the U.S. positioned as the core site. We are improving links and global collaboration, increasing development speeds, and training staff capable of driving forward global projects. We are engaged in a major global Phase 3 clinical study in the U.S., Japan, and Europe on DE-109 (sirolimus) for the treatment of uveitis. In July 2012, we started Phase 1/2a studies in the U.S. on DE-117 (licensed in from Ube Industries, Ltd.) for the treatment of glaucoma and ocular hypertension. Our goal is to obtain global manufacturing and marketing approval for this prostaglandin derivative treatment with a novel mechanism of action.

In order to meet the wide-ranging treatment needs found in the clinical setting, we are making effective use of existing compounds and creatively managing product life cycles<sup>2</sup>, for example by expanding indications and adding formulations, new methods of administration and dosages. In

October 2012 in Japan and June 2013 in Europe, we filed for manufacturing and marketing approval of the combination drug DE-111 (tafluprost/timolol maleate) for the indications of glaucoma and ocular hypertension. In January 2013, we were granted manufacturing and marketing approval in Japan for DE-118 (tafluprost) in a preservative-free, unit-dose, single-use formulation. And in November 2012, we also applied for manufacturing and marketing approval in Japan for DE-114 (epinastine HCl) for the indication of allergic conjunctivitis.

We are making steady progress in Phase 3 studies on Cyclokat (ciclosporin) that is expected to be the first prescription treatment for dry eye in Europe. Santen S.A.S., which we acquired in fiscal 2011, is playing a central role in the development of Cyclokat, which uses our proprietary drug formulation technology Novasorb<sup>3</sup>. We are applying this technology to other existing pipeline compounds, thereby reconfirming our strong position as a specialized ophthalmic pharmaceutical company.

1. Proof of Concept (POC) is the realization of a certain method or ideas to demonstrate efficacy or safety in clinical trials.
2. Aligning one compound to treatment needs over the long term and augmenting through variations in use, dosage, formulation and combination products to increase product value.
3. Novasorb aids rapid absorption of ophthalmic solutions over the ocular surface by applying a positive electric charge to an ophthalmic emulsion. This causes the drug to be attracted to the negatively charged ocular tissues and helps to protect the eye's surface.

Pipeline of Main Prescription Pharmaceuticals

Therapeutic Field	Phase 1	Phase 2		Phase 3	NDA Filed	Approved/Launched
Glaucoma		DE-117 EP2 agonist			China <b>DE-085</b> Tafluprost	Japan, etc. <sup>4</sup>
		DE-090 Lomerizine HCl			DE-111 Tafluprost/ timolol maleate	DE-118 Tafluprost
Corneal and Conjunctival Epithelial Disorders	U.S. Peptide combination	DE-105	Japan		China <b>DE-089</b> Diquafosol sodium	Korea Japan
		U.S. Cyclokat Ciclosporin	Europe			
Retinal and Uveal Disorders				DE-109 Sirolimus		
			DE-102 Betamethasone			
Ocular Infections/Allergy/Rheumatoid Arthritis		DE-098 Anti-APO-1 antibody			DE-114 Epinastine HCl	
			Vekacia Ciclosporin			

As of August 6, 2013

4. Asia, Europe, Latin America, Australia, and the U.S.

## Domestic Operations

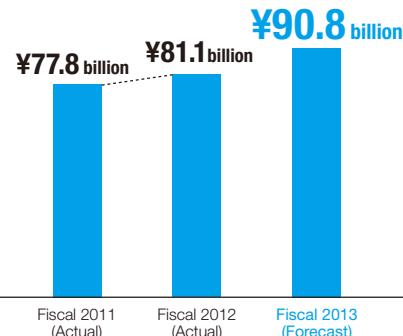
**We are focusing on maximizing the value generated by new products as we aim to achieve continuous future growth in domestic operations.**

In the domestic prescription ophthalmic business, we have been enhancing our strength as a specialty company, for example, by ensuring MRs have a wider range of specialized ophthalmology knowledge covering both the anterior and posterior chambers of the eye to improve their responsiveness. This has allowed us to provide medical information targeted to the changing therapeutic needs of patients. At the same time, we focused on the market penetration of new drugs that will act as future growth drivers. Thanks to these efforts, we were able to absorb the impact of NHI drug price revisions and net sales rose 4.3% year on year to ¥81.1 billion. In addition, we achieved our target for fiscal 2013 one year earlier than planned.

In the field of glaucoma, we grew our domestic share by 2.0 percentage points year on year to 30.4%. This was driven by steady growth in sales of glaucoma and ocular hypertension treatments *Tapros* and *Cosopt*, securing our position as the market leader. We also remain in a strong position in the field of corneal and conjunctival epithelial disorders, capturing a 74.6% share of the domestic market. Sales of our mainstay product *Hyalein* (sodium hyaluronate) fell 7.2% year on year due to the NHI drug price revisions, but sales of *Diquas*, a treatment for dry eye with a different mechanism of action, surged 95.5%.

Santen moved into the field of retinal disorders with the November 2012 launch of *EYLEA* for wet AMD, based on a co-promotion agreement with Bayer Yakuhin, Ltd. We are drawing on our organizational capabilities, ophthalmology expertise and our competitive strengths in the prescription ophthalmic pharmaceutical market, to contribute to the treatment of back-of-the-eye diseases. This entry into the retinal space is exciting to me as I feel that it is our responsibility as a specialized ophthalmic pharmaceutical company to treat the full range of all ophthalmic diseases including the unmet needs in the retinal space.

**Prescription Ophthalmic Pharmaceutical Sales in Japan and Fiscal 2013 Forecast**



## Operations in Asia

**The Suzhou Plant began integrated production of some products from July 2012. Looking ahead, we aim to further raise our presence in the entire fast-growing Asian market.**

In Asia, sales on a yen basis grew 27.6% year on year to ¥8.6 billion in fiscal 2012, driven by significant sales growth in China and increased penetration of the Korean market.

We expect the Chinese prescription ophthalmic pharmaceutical market to continue growing at around 20% per annum through 2020 and consider this market to be a key in driving our global business. We are therefore bolstering our business platform through in-house manufacturing and direct marketing in China. We believe that Santen will gain a competitive advantage in China by providing products and services imbuing value as well as quality detailing to provide information tailored to the needs of medical professionals.

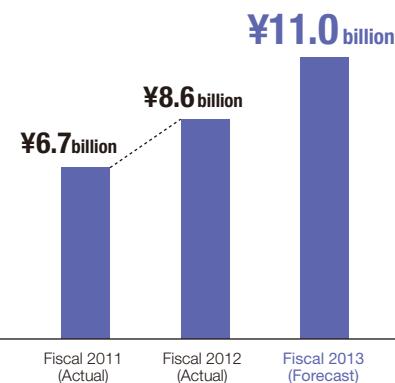
In July 2012, our plant in Suzhou, China, was licensed for integrated production covering everything from formulation and filling through packaging. We now have a system capable of supplying products in a timely manner that meets the needs of the Chinese market. The start of integrated production at the Suzhou Plant is an important step towards optimizing our global operations as part of the goal to "establish systems for global product supply and quality assurance" in our long-term strategic vision for 2020. We currently have a Chinese sales force of over 200 MRs, the second largest after Japan. Having operated in China for nearly 10 years and trained our staff during that time, our locally employed MRs have grown significantly such that they are now providing information based on local therapeutic needs.

In 2009, Santen began using its own MRs in China; filed for marketing and manufacturing approval for tafluprost to treat glaucoma and ocular hypertension in January 2011; and now markets products across Asia in Hong Kong, Korea, Indonesia, and Singapore. We were granted Korean

manufacturing and marketing approval in December 2011 for diquafosol sodium (sold as *Diquas* in Japan) to treat dry eye and are in the process of filing for approval in China. As well as establishing a presence in the Chinese market, we are working to capture the No.1 position across Asia.



Sales in Asia and Fiscal 2013 Forecast



## Globalized Manufacturing System

We are building a manufacturing system capable of competing on global terms. Our global production system is based on four plants: the main factory in Noto, Japan; the Shiga Product Supply Center<sup>1</sup>, our core global facility in Shiga, Japan; and overseas plants in Suzhou, China, and Tampere, Finland. These four facilities enable Santen to maintain stable supplies and high-level quality control while also supplying the needs of different regions.

1. Name changed from Shiga Plant on July 1, 2013

## Operations in Europe

**In addition to Eastern Europe, Russia and other emerging markets, as well as Northern Europe, we are expanding our business platform in Germany and other developed country markets.**

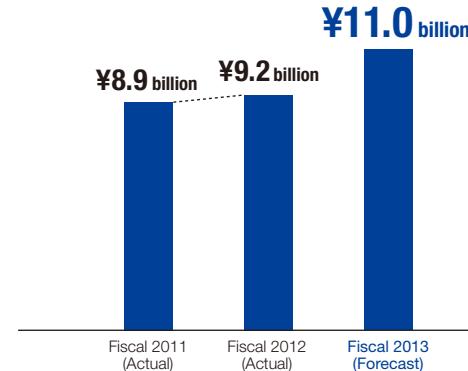
In Europe, sales on a yen basis grew 3.6% year on year to ¥9.2 billion in fiscal 2012. We achieved further market penetration, particularly in Germany, with the new product *Taflotan* (tafluprost) for glaucoma and ocular hypertension.

The European prescription ophthalmic pharmaceutical market has achieved sustained growth, boosted by economic growth in emerging markets in Eastern Europe and Russia where Santen has a strong business platform. We aim to meet the targets in the Fiscal 2011–2013 Medium-Term Management Plan by creating a highly profitable business in Europe and working to expand our market share with the promotion of drug usage through the provision of medical information, an area in which we excel.

Since its launch in 2008, our growth driver *Taflotan* has been widely supported by European ophthalmologists, developing into the treatment of choice for glaucoma and ocular hypertension in a short period of time. In 2012, *Taflotan* was selected by 1,500 German physicians from a range of specialties as the Most Innovative Glaucoma Product 2012 in the category of ophthalmology. This award is organized by the German magazine *PharmaBarometer* and is one of the most famous awards in healthcare.

In fiscal 2013, we are working to become more competitive in Europe, stepping up our marketing activities across all of Europe but with a particular focus in Germany. In R&D, we aim to maximize the synergies from the Santen S.A.S. merger, strengthening our development pipeline and increasing the value of existing products, to make further advances in the European market.

Sales in Europe and Fiscal 2013 Forecast



## Corporate Social Responsibility (CSR) Activities

**Based on Santen's Values, we are working as one team to enhance CSR activities, pursuing a true customer focus.**

We contribute to society through sound business activities based on Santen's Values. We think that it is vital to enhance the understanding of CSR by all our Group employees.

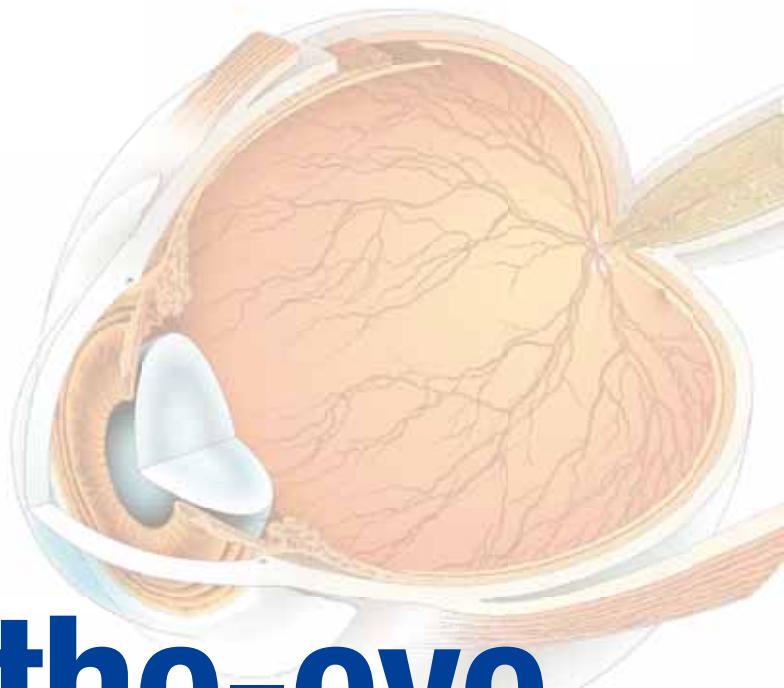
Through the Santen Code of Practice, we have clarified the standard of conduct required in our operations; defined our own core fields for CSR promotion, which draws on the ISO 26000<sup>2</sup> international standard on social responsibility; and expanded the range of our activities that are consistent with international requirements.

To become a specialized pharmaceutical company with a global presence, as outlined in our long-term strategic

vision for 2020, we are working to expand the Company and grow earnings, but we also aim to achieve these goals through the pursuit of CSR. We will be a responsible corporate citizen if we successfully integrate and engage in both business and CSR activities, and this will enable us to achieve our strategic vision. We think the development of every single employee is vital to drive the achievement of our long-term strategic vision, so we are actively engaged in employee training.

2. ISO 26000 was issued by the International Organization for Standardization (ISO) to provide guidance on social responsibility. It is applicable not only to corporations but also to all organizations, including governments, schools, and NGOs.

# Rising to the Challenge of Satisfying Unmet Medical Needs



Eyeing Further Specialization

## Back-of-the-eye Diseases

### Main Back-of-the-Eye Diseases

- Age-related macular degeneration
- Uveitis
- Behcet's disease
- Detached retina
- Diabetic retinopathy
- Macular edema
- Infectious intraocular inflammation

As a specialty company in the eye and other specific fields, we provide products and services to the prescription ophthalmic pharmaceutical market to satisfy a wide range of therapeutic needs, particularly front-of-the-eye diseases such as dry eye and glaucoma.

We have established ourselves as the No.1 ophthalmic pharmaceutical company in Japan.

We are now providing products and services for back-of-the-eye diseases, with the launch of *EYLEA* (afibbercept [genetical recombination]) in Japan to treat wet age-related macular degeneration (wet AMD).

The number of patients needing retinal disorder treatment is growing rapidly, driven by population aging and other factors.

### Effective New Drugs Required for Underserved Back-of-the-Eye Field

There are unmet medical needs for many back-of-the-eye diseases, including wet AMD, diabetic retinopathy, and macular edema. Patients around the world live in the hope that groundbreaking new treatments will be developed. Overseas, retinal disorder markets are growing due to high unmet medical needs. Santen recognizes the strong potential in these markets to drive its growth going forward.

AMD involves abnormalities appearing in the macular area, a region located in the center of the retina that is vital for vision. It occurs in dry and wet forms. With wet AMD, abnormal blood vessels form below the retina in the macular area. Bleeding and leaking from these vessels cause retinal damage and functional impairment. Patients find it hard to see in the center of their vision, resulting in a sharp decline in Quality of Life (QOL).

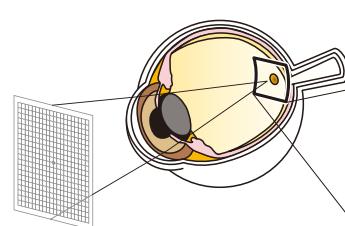
Research has identified vascular endothelial growth

factor (VEGF) as the substance that causes blood vessel formation and development and the leaking of blood and exudate. VEGF plays a vital role in the formation and maintenance of normal blood vessels, but it also triggers wet AMD by stimulating the development of unnecessary blood vessels.

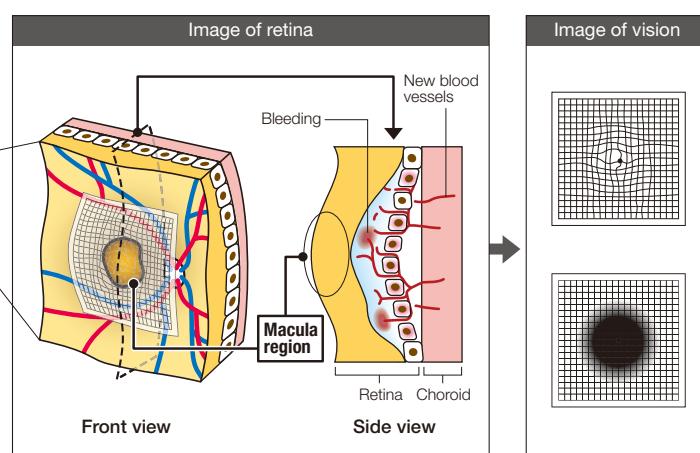
Around 20 years ago there were no effective treatments for wet AMD, but there have been significant advances in therapeutic methods since then, including laser therapy, antibody drugs, and biopharmaceuticals. Due to the aging population and other factors, the Japanese market for retinal disorder treatments has grown at around 20% per annum and now accounts for approximately 10% of the total prescription ophthalmic pharmaceutical market.

#### Mechanism of Wet AMD

These illustrations are images.



In wet AMD, the macular area of the retina is damaged by bleeding and leaking from choroidal blood vessels, resulting in distortion and loss of central vision.



## Helping patients in the retinal disorder field with the highest unmet needs as a specialized ophthalmic pharmaceutical company.

### Providing a New Treatment Option for the Rapidly Increasing Number of Wet AMD Patients

Santen provides products and services to meet global therapeutic needs in the field of ophthalmology. Our mission is to help improve patients' QOL. We have positioned back-of-the-eye diseases, including retinal disorders, as one of the highest priority areas where there are substantial unmet medical needs.

The back-of-the-eye disease AMD is the fourth most common cause of vision loss in Japan. Patient numbers are increasing sharply as the population ages, but only a small proportion of patients receive treatment. With few pharmaceutical options for the treatment of wet AMD, healthcare professionals have long hoped for new treatments to become available.

To broaden the treatment options available, Santen has launched *EYLEA* in Japan, a new treatment for wet AMD. As a specialized ophthalmic pharmaceutical company, we consider it extremely important to provide healthcare professionals with products needed by patients. Our goal is to continue supplying unique products, information, and services that satisfy patients' unmet needs, in a bid to contribute to better treatment.



Sadatoshi Furukado  
Director  
Executive Corporate Officer  
Japan Business and Human Resources Development,  
Head of Sales and Marketing Division,  
Prescription Pharmaceuticals



Intravitreal VEGF Inhibitor *EYLEA*

## Enhancing Patients' QOL with New Treatments

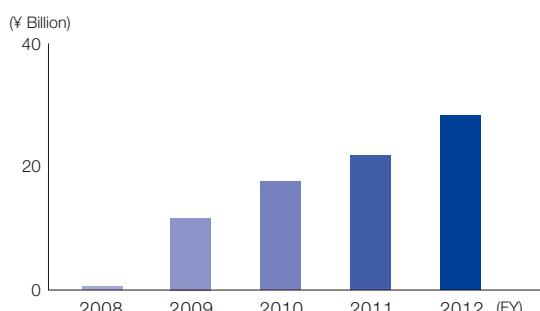
The Intravitreal VEGF Inhibitor *EYLEA*, which was co-developed by Regeneron Pharmaceuticals, Inc. and Bayer HealthCare, inhibits the action of VEGF that is one of the causes of wet AMD. Intravitreal injections of *EYLEA* improves symptoms by suppressing the growth of, and stopping bleeding and leakage from, the new blood vessels.

*EYLEA* is expected to maintain and improve sight through a proactive treatment regimen: once monthly during the first three months (initial phase) and usually once every two months thereafter (maintenance

phase). *EYLEA* is rapidly penetrating the market because of its superior product profile and our ophthalmological expertise in the provision of quality medical information.

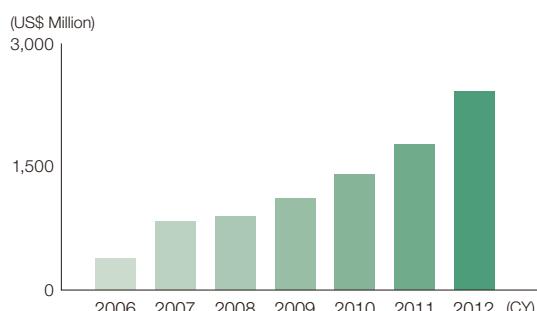
Through the experience with *EYLEA*, Santen will develop an even more thorough understanding of therapeutic needs in the field of retinal disorders. We are working with our sales partner Bayer Yakuhin, Ltd. to support better patients' QOL through the provision of quality medical information.

### Sales of Intravitreal VEGF Inhibitors in Japan



Source: Santen analysis based on IMS-JPM data

### Sales of Intravitreal VEGF Inhibitors in the U.S.



Source: Based on companies' actual results data for ranibizumab and afibercept intravitreal injection

## Message

### I Am Confident We Can Maximize *EYLEA*'s Product Value Through Partnership with Santen

Since it was first approved in the U.S. in 2011, *EYLEA* has been successfully marketed in Australia, Latin America, Europe and some other countries and regions. *EYLEA* has been well received in these markets, serving as a new treatment option that meets the therapeutic needs of patients around the world. In Japan, *EYLEA* has seen a smooth uptake in the market in just a few months after its launch, and now contributes to the treatment of many patients.

As a specialty company with an unshakeable No.1 share in the Japanese market for prescription ophthalmic pharmaceuticals, Santen is the

ideal partner for us as we enter the field of ophthalmology. We feel assured and encouraged by the fact that Santen has established a strong relationship with some 13,000 ophthalmologists across Japan, as well as by the company's in-depth understanding of the needs of the medical community. I am confident that our partnership with Santen will further accelerate the market penetration of *EYLEA* in Japan.

Dr. Carsten Brunn  
President, Bayer Yakuhin, Ltd.



## Taking on the challenge of establishing a presence in a new treatment field based on relationships of trust with ophthalmologists across Japan.

### Demonstrating Our Strengths as a Specialized Ophthalmic Pharmaceutical Company

EYLEA has penetrated the Japanese market much faster than expected. Immediately after launch, the drug was adopted by university hospitals and other



Takeshi Ito  
Corporate Officer  
Head of Prescription, Pharmaceuticals Sales Department,  
Sales and Marketing Division, Prescription Pharmaceuticals

facilities already using other intravitreal VEGF inhibitors. Santen's sales in Japan in fiscal 2012 reached ¥3,183 million in only four months from launch. These strong results serve to highlight the significant unmet medical needs for wet AMD in Japan. We expect sales in fiscal 2013 to reach ¥9,852 million.

As well as EYLEA's unique product profile, we attribute this success to our knowledge and expertise built up over many years in the field of ophthalmology and the close collaboration with our sales partner Bayer Yakuhin, Ltd. We have also developed relationships of trust with ophthalmologists over many years and have received feedback from many doctors on the need for a new therapeutic option for wet AMD. EYLEA has penetrated the Japanese market extremely rapidly, even compared with overseas markets, and we feel that we have been able to meet the expectations of patients and healthcare professionals alike. Looking ahead, we will continue to strive to supply products and services to satisfy unmet medical needs so as to allow more patients access to therapies.

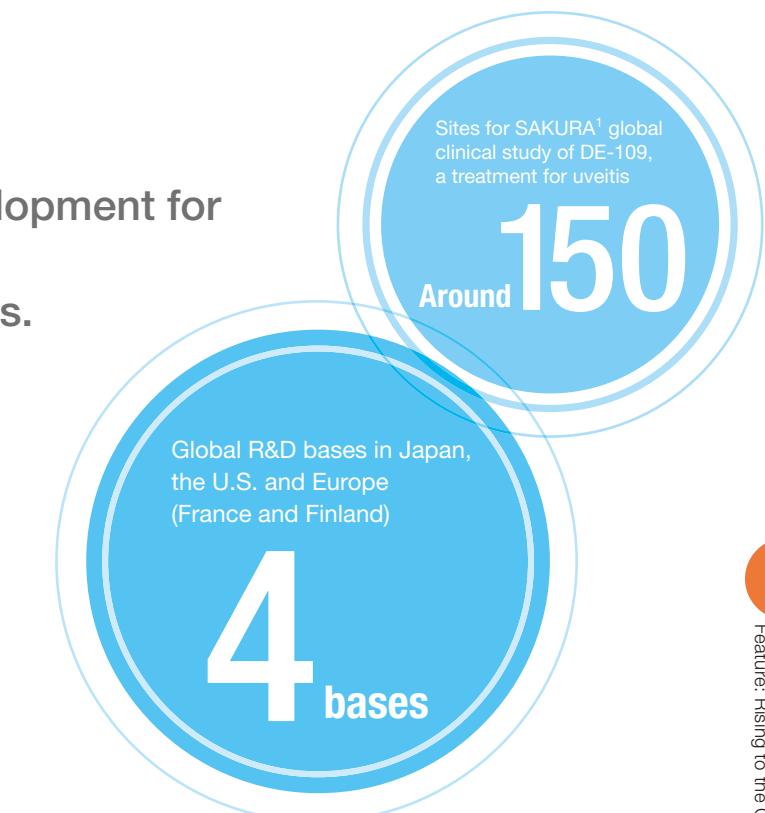


## Promoting global clinical development for creating products based on global medical treatment needs.

### Developing Competitive New Drugs to Address Needs for Treating Retinal Disorders

In the Fiscal 2011–2013 Medium-Term Management Plan, Santen proposed a strategic objective of “promoting globally oriented research and development.” In addition to corneal disorders and glaucoma, areas where Santen has an especially strong presence, we have defined retinal disorders as a key area and are developing products to meet global medical needs in back-of-the-eye diseases.

DE-109 has been assigned orphan drug status by the regulatory authorities in the U.S. and Europe for the indication of non-infectious posterior uveitis. A project team has been formed in the U.S. that is managing the SAKURA<sup>1</sup> Phase 3 global study at approximately 150 sites. DE-102 (betamethasone) is undergoing Phase 2/3 studies in Japan for the indication of macular edema associated with diabetes and BRVO<sup>2</sup>. Pre-clinical studies demonstrated sustained efficacy when injected around the affected area. Manufacturing methods are being developed for commercial-scale production, a partnership agreement has been signed with Oakwood Laboratories of the U.S., and we are making every effort to successfully



develop this product as quickly as possible.

Through our experience of providing medical information and detailing for EYLEA, we are gaining an even deeper understanding of treatment needs, including feedback on treatment methods and challenges with AMD and expectations for product development. We reflect on this feedback from patients and healthcare professionals on their experience with treatment methods and use this information when developing new pharmaceuticals to support better visual and physical health for patients around the world.

1. Study Assessing double-masKed Uveitis tReAtment

2. branch retinal vein occlusion

### Message

#### I Have High Expectations for Santen’s Efforts in Retinal Disorders

Wet age-related macular degeneration (wet AMD) ranks as the fourth leading cause of acquired blindness in Japan. Around 10 years ago, the number of patients was estimated at approximately 330,000 people. But the number of patients has increased rapidly since then to double that number today due to aging and other factors. Treatment needs are thus rising.

Up to now, there were only two intravitreal VEGF (vascular endothelial growth factor) inhibitors that were effective in treating wet AMD. However, the launch of EYLEA has broadened treatment

options, raising expectations for maintaining and improving patients’ sight. As a specialist, I am delighted that a new drug has been developed for retinal disorders where there are high unmet medical needs.

I hope that Santen will continue to draw on its knowledge as a specialized ophthalmic pharmaceutical company to develop more outstanding pharmaceuticals sought by patients.

Mitsuko Yuzawa, M.D.  
Professor, Division of Ophthalmology,  
Department of Visual Sciences,  
Nihon University School of Medicine



# Research and Development

Santen began conducting R&D under a new management structure in 2013.

Under this structure, Santen will work to expedite the development process for new drugs that satisfy unmet medical needs.

**Every effort is being made to quickly and efficiently transform the Santen Group into a fully integrated, global specialized company with a worldwide presence.**

Naveed Shams, M.D., Ph.D.

Corporate Officer, Chief Science Officer, President & CEO, Santen Inc.

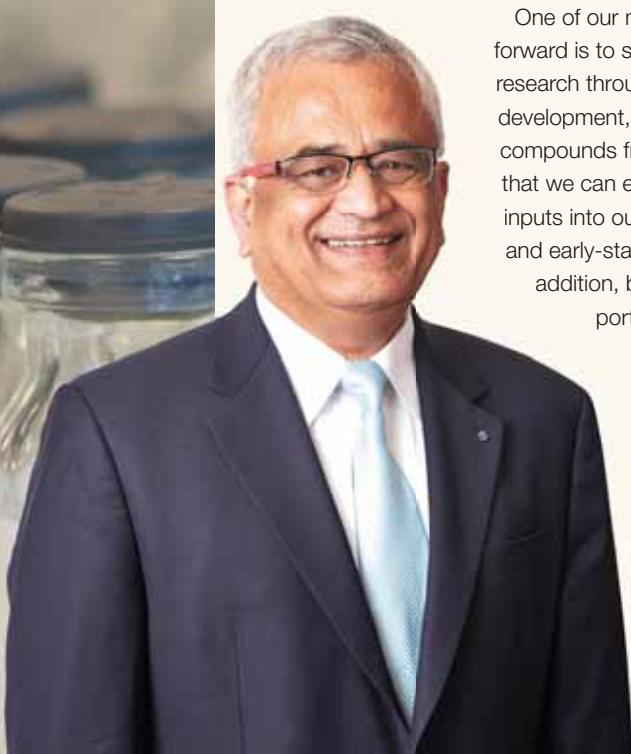
## Better Strategic Planning from a Development Perspective

Based on its strategic business objectives, Santen transformed its R&D organization during fiscal 2012. This included anchoring global clinical development and medical affairs functions in the U.S. In addition, our European subsidiary, Santen S.A.S. (formerly Novagali Pharma S.A.S.), was fully integrated with the Santen Group in January 2012. This achievement will allow us to leverage our expertise in ophthalmic formulations to effectively and efficiently formulate best-in-class molecules for accelerated development worldwide.

During fiscal 2012, we also continued to improve our decision-making processes whilst improving collaboration and work ethics across R&D worldwide. In fiscal 2013, translational studies to establish POC<sup>1</sup> will continue to be conducted in the U.S. These integrations will improve decision-making, consolidate resources, and maintain the cost of development in an adequate manner. In order to accelerate the development of products, Santen will focus on developing "differentiated" products based on a deep understanding of unmet medical needs in all regions. To reduce risk and accelerate development we will also develop a global network of partners.

One of our major challenges going forward is to supplement our in-house research through network-based drug development, which is to in-license compounds from external sources so that we can expand the number of inputs into our screening programs and early-stage clinical studies. In

addition, based on our product portfolio strategy for each region, we aim to maximize returns on R&D investment by using benefit and risk assessments to gauge the value of each product.



In April 2013, we began a new system designed to further speed up global clinical development. As Chief Scientific Officer (CSO), it is my job to develop a global strategic and tactical R&D plan. The plan will consist of short-, medium- and long-term objectives. The immediate focus will be on the fiscal 2014 through fiscal 2017 time frame. The cornerstone of the plan will be to better understand unmet medical needs in the various regions of interest to Santen. This will be followed by prioritization with an eye on deliverables to ensure that business objectives are met. As time is of the essence, strategies to accelerate development while keeping costs to a minimum will be developed and implemented.

1. Proof of Concept (POC) is the realization of a certain method or idea to demonstrate efficacy or safety in clinical trials.

## Maximizing Product Value Based on Specific Market Needs

Santen is engaged in proprietary drug discovery research mainly in the three fields of corneal disorders, glaucoma and retinal disorders. Since medical needs vary significantly in different markets around the world, developing a competitive drug portfolio must be driven by the needs of customers and not by the products if we are to extract maximum therapeutic value. Currently, we are planning to introduce a system to enable us to gain scientific data from ophthalmologists and patients worldwide so that we can better define our investment priorities based on an idea of customers' real needs.



## Executing strategy-based initiatives to develop competitive products

Takashi Kaneko, M.D., Ph.D.

Corporate Officer, Head of Research and Development Division



## Forging Seamless Collaboration between Bases in Japan, the U.S. and Europe Based on Synchronized Sharing of R&D Results and Development Progress

Within Santen's new R&D system, my role is to manage globally the execution of specific measures based on our product portfolio strategy. In fiscal 2012, we created a system that makes the most of our diverse, specialist resources based on seamless links between bases in Japan, the U.S. and Europe, notably at pre-clinical stages. We are also pushing on with our "KANAME" project, which is enhancing R&D efficiency by capturing the progress and results of development projects and related issues across regions. Continuing to develop our organization efficiently and increase the productivity of our global development will remain a key priority for us going forward.

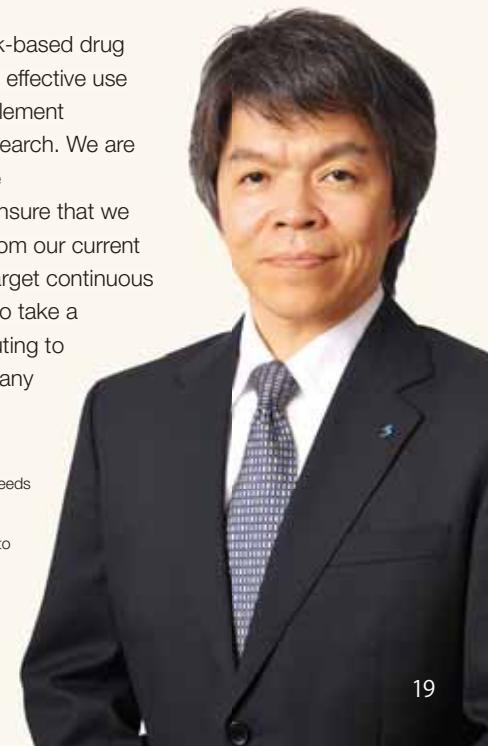
## Targeting Continuous Growth through Steady Development of the Late-Stage Clinical Pipeline

We are making steady progress in the development of our late-stage clinical pipeline. In the field of glaucoma, we applied for manufacturing and marketing approval for our combination drug DE-111 (tafluprost/timolol maleate) in Japan and Europe in October 2012 and June 2013,

respectively. DE-118 (tafluprost) in a preservative-free, unit-dose, single-use formulation gained Japanese regulatory approval in January 2013. In the field of retinal disorders, we are conducting Phase 3 clinical trials in the U.S., Japan and Europe with DE-109 (sirolimus). In the field of corneal and conjunctival epithelial disorders, Phase 3 clinical trials are progressing steadily with Cyclokat (ciclosporin), which is indicated for the treatment of severe dry eye.

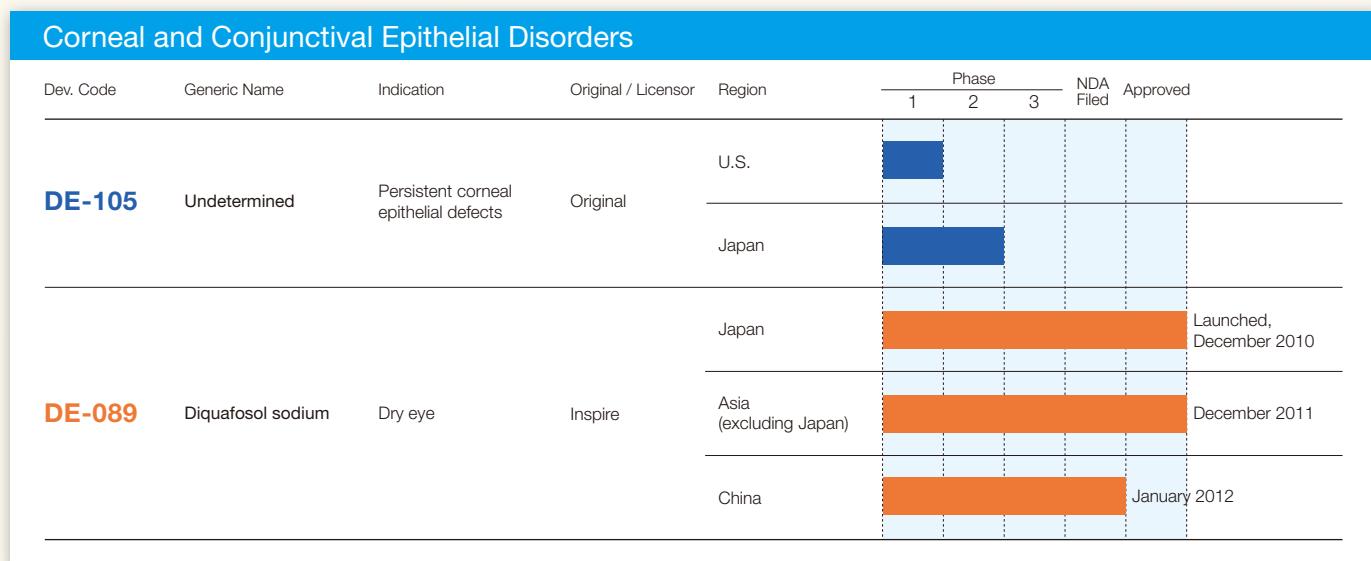
We are applying a "network-based drug discovery" approach to make effective use of external resources to supplement Santen's original in-house research. We are also using a product life cycle management<sup>2</sup> approach to ensure that we maximize the value derived from our current portfolio of compounds. To target continuous growth, we plan to continue to take a variety of steps while contributing to medical treatment as a company specializing in ophthalmic pharmaceuticals.

2. Aligning one compound to treatment needs over the long term and augmenting through variations in use, dosage, formulation and combination products to increase product value.



## Pipeline of Prescription Pharmaceuticals (Clinical Development)

█ Global product █ Japan (Asia) product



As of August 6, 2013

## Corneal and Conjunctival Epithelial Disorders

### DE-105 (generic name: undetermined)

A new drug candidate that is expected to provide high levels of safety for persistent corneal epithelial defects compared with existing therapy, DE-105 helps repair corneal epithelial defects by accelerating corneal epithelial migration. Phase 2 clinical trials have been completed in Japan and preparations are being made for Phase 2 clinical trials in the U.S.

### DE-089 (generic name: diquaferon sodium)

A treatment for dry eye that stimulates the ocular surface to secrete mucin and tear fluid, DE-089 offers a different mechanism of action from Hyalein (sodium hyaluronate), a treatment for corneal and conjunctival epithelial disorders. It was launched as a dry eye treatment in Japan under the name Diquas in December 2010. Manufacturing and marketing approval was received in Korea in December 2011. An NDA has been filed in China.

## Glaucoma

### DE-085 (generic name: tafluprost)

A prostaglandin derivative for the treatment of glaucoma and ocular hypertension, DE-085 increases uveoscleral outflow of the aqueous humor and shows a potent and stable IOP-lowering effect. DE-085 was launched in Germany in June 2008 and in Japan in December 2008. It is currently directly marketed in 23 countries throughout Europe as well as four countries in Asia. An NDA has been filed in China.

A licensing agreement with U.S.-based Merck & Co., Inc. was concluded in April 2009 that granted sales rights in Western Europe (excluding Germany), North America, South America and Africa. Tafluprost has been marketed by Merck & Co., Inc. in the United Kingdom, Spain, Italy, the U.S. and certain other countries since September 2009. Incorporating sales under this licensing agreement, tafluprost is currently sold in over 60 countries worldwide.

### DE-111 (generic name: tafluprost/timolol maleate)

DE-111 is a combination drug of tafluprost, a prostaglandin derivative and timolol maleate, a beta-adrenergic receptor blocker drug for the treatment of glaucoma and ocular hypertension. Applications for manufacturing and marketing approval for the treatment of glaucoma and ocular hypertension were filed in Japan and Europe in October 2012 and June 2013, respectively.

### DE-117 (generic name: undetermined)

A prostaglandin EP2 agonist with a new mechanism of action. DE-117 is in Phase 1/2a clinical trials in the U.S.

### DE-118 (generic name: tafluprost)

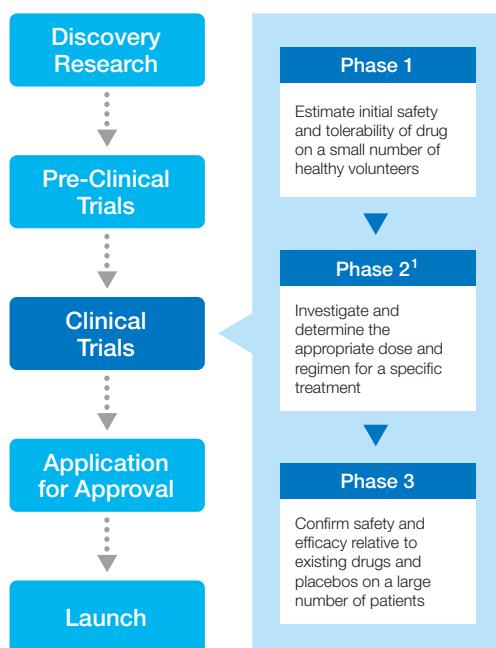
A prostaglandin derivative for the treatment of glaucoma and ocular hypertension, DE-118 is a preservative-free, unit-dose, single-use type product. Manufacturing and marketing approval was received in Japan in January 2013.

### DE-090 (generic name: lomerizine HCl)

A new type of glaucoma treatment which inhibits the progression of visual field defects, DE-090 is in Phase 2 clinical trials being conducted in Japan. It is the only calcium antagonist being developed as an oral glaucoma treatment. Compared to NMDA receptor antagonists, systematic adverse drug reactions are mild, offering an excellent safety profile. The compound is also marketed by MSD K.K. in Japan as a migraine treatment drug.

## About Research and Development

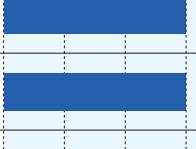
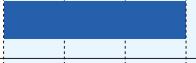
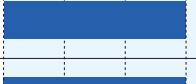
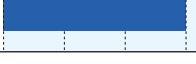
After passing pre-clinical trials for safety and efficacy, new drug candidates are put through the clinical trial phases outlined below. Upon receiving manufacturing and marketing approval, they can be sold as prescription pharmaceuticals.



1. In the initial stage of Phase 2, POC (Proof of Concept) is tested and safety and efficacy evaluated.

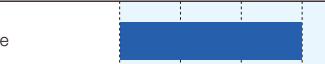
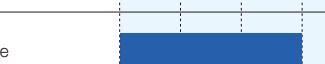
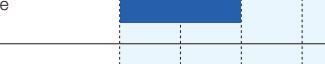
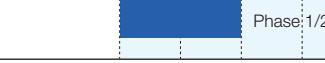
## Pipeline of Prescription Pharmaceuticals (Clinical Development)

 Global product  Japan (Asia) product

Retinal and Uveal Disorders						
Dev. Code	Generic Name	Indication	Original / Licensor	Region	Phase 1 2 3	NDA Filed Approved
<b>DE-102</b>	Betamethasone	Macular edema associated with diabetes and BRVO <sup>1</sup>	Co-development with Oakwood	Japan		Phase 2/3
				U.S.		
<b>DE-109</b>	Sirolimus	Uveitis	Original	Japan		
				Europe		

1. branch retinal vein occlusion

Ocular Infections/Allergy						
Dev. Code	Generic Name	Indication	Original / Licensor	Region	Phase 1 2 3	NDA Filed Approved
<b>DE-114</b>	Epinastine HCl	Allergic conjunctivitis	Nippon Boehringer Ingelheim	Japan		November 2012

Santen S.A.S.'s Pipeline of Prescription Pharmaceuticals						
Dev. Name	Generic Name	Indication	Original / Licensor	Region	Phase 1 2 3	NDA Filed Approved
<b>Cyclokat</b>	Ciclosporin	Severe dry eye	Original	Europe		
				U.S.		
<b>Vekacia</b>	Ciclosporin	Vernal keratoconjunctivitis	Original	Europe		
<b>Catioprost</b>	Latanoprost	Glaucoma Ocular hypertension	Original	Europe		
<b>Cortiect</b>	Dexamethasone palmitate	Diabetic macular edema	Original	U.S.		Phase 1/2

\*Catioprost and Cortiect are under project evaluation

Rheumatoid Arthritis						
Dev. Code	Generic Name	Indication	Original / Licensor	Region	Phase 1 2 3	NDA Filed Approved
<b>DE-098</b>	Undetermined	Rheumatoid arthritis	Janssen Biotech	Japan		

As of August 6, 2013

## Retinal and Uveal Disorders

### DE-102 (generic name: betamethasone)

A steroid microsphere product for sustained release injection, DE-102 is in Phase 2/3 clinical trials in Japan as a treatment for macular edema associated with diabetes and BRVO<sup>1</sup>. Pre-clinical studies demonstrated sustained efficacy when injected around the affected area. Santen is collaborating with Oakwood Laboratories of the U.S. in the development of the microsphere delivery platform for this product.

1. branch retinal vein occlusion

### DE-109 (generic name: sirolimus)

An intravitreal injection with immunosuppressive effect and anti-angiogenic effect, etc. In June 2010, Santen acquired global rights from U.S.-based MacuSight, Inc. for the development, manufacturing, and marketing of sirolimus. Phase 3 clinical trials were already underway for uveitis in the U.S., Japan and Europe.

## Ocular Infections/Allergy

### DE-114 (generic name: epinastine HCl)

An H<sub>1</sub> receptor antagonist with a membrane-stabilizing function as a treatment for allergic conjunctivitis, DE-114 was licensed from Nippon Boehringer Ingelheim Co., Ltd. An application was filed in Japan in November 2012 for manufacturing and marketing approval.

## Santen S.A.S.'s Pipeline of Prescription Pharmaceuticals

### Cyclokat (generic name: ciclosporin)

This is a topical ophthalmic emulsion which improves symptoms and signs of severe dry eye by immunosuppressive effect. Novasorb technology (cationic emulsion technology) has enhanced ocular tissue absorption. It is currently in Phase 3 clinical trials in Europe and Phase 2 clinical trials have been completed in the U.S.

### Vekacia (generic name: ciclosporin)

This is a topical ophthalmic emulsion which improves vernal keratoconjunctivitis symptoms by immunosuppressive effect. Novasorb technology has enhanced ocular tissue absorption. It is in Phase 3 clinical trials in Europe.

## Product Life Cycle Management

Product life cycle management refers to aligning one compound to treatment needs over the long term by leveraging drug formulation and other production technology and augmenting through variations in use, dosage, formulation and combination products to increase product value. Focusing on product life cycle management from the development stage, Santen seeks to maximize the value of products by making more effective use of existing compounds and through global business expansion that capitalizes on different medical needs in each region.

Glaucoma and ocular hypertension

### DE-085

Tafluprost

Launched in Japan and Europe in 2008, tafluprost is now sold in over 60 countries worldwide.

### DE-111

Tafluprost/timolol maleate

A fixed dose combination of different mechanism of actions  
Applications for manufacturing and marketing approval were filed in Japan and Europe in 2012 and 2013, respectively.

### DE-118 Tafluprost

A preservative-free, unit-dose, single-use formulation  
Launched in Europe in 2008 and the U.S. in 2012 (licensed out to Merck & Co., Inc.). Manufacturing and marketing approval was obtained in Japan in January 2013.

## Catioprost (generic name: latanoprost)

This is a topical ophthalmic emulsion of a prostaglandin F<sub>2α</sub> derivative, for the treatment of glaucoma and ocular hypertension. It is currently under project evaluation.

### Cortiect (generic name: dexamethasone palmitate)

An intravitreal injection with anti-inflammatory effect. It is currently under project evaluation.

## Rheumatoid Arthritis

### DE-098 (generic name: undetermined)

A joint injection that induces apoptosis in diseased joints of rheumatoid arthritis patients, DE-098 is an anti-APO-1 antibody in-licensed from Janssen Biotech, Inc. for the treatment of rheumatoid arthritis. We are currently considering the next development plan based on the results of Phase 2 clinical trials in Japan.

# Review of Operations

Delivering Needed Pharmaceuticals to Patients and Their Loved Ones

## [Domestic Operations]

### Prescription Ophthalmic Pharmaceuticals

Fiscal 2012 Sales

**¥81,125 million +4.3%**

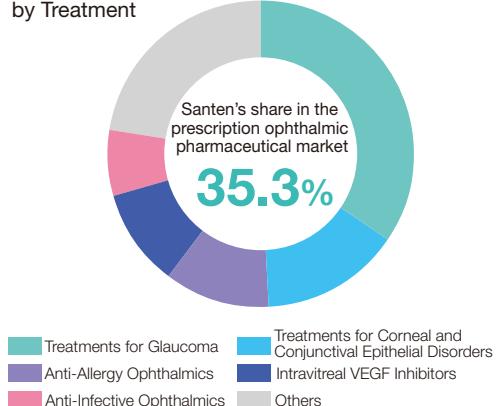
The Japanese prescription ophthalmic pharmaceuticals market grew 7.3%, to ¥273,405 million in fiscal 2012, due to growth in sales of products for retinal disorders and corneal and conjunctival epithelial disorders. Santen's domestic prescription ophthalmic pharmaceutical sales increased 4.3%, to ¥81,125 million. This increase was due to our advancement of promotional activities in which our MRs provided individual doctors and medical facilities with scientific information tailored to their changing needs. Based on these results, Santen maintained its top share of the domestic prescription ophthalmic pharmaceutical market, which currently stands at 35.3%.

#### Prescription Ophthalmic Pharmaceutical Market Trends

Market Size  
(¥ Billion)

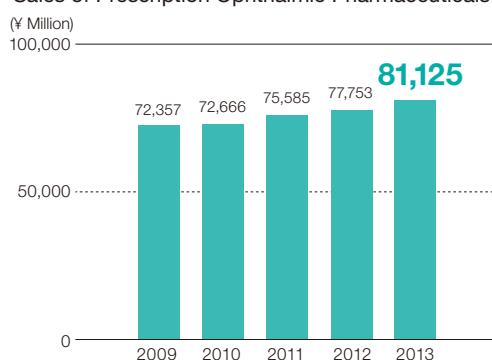


Market Composition by Treatment



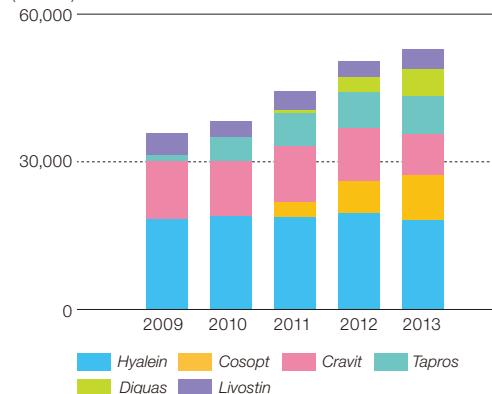
Sales of Prescription Ophthalmic Pharmaceuticals

(¥ Million)



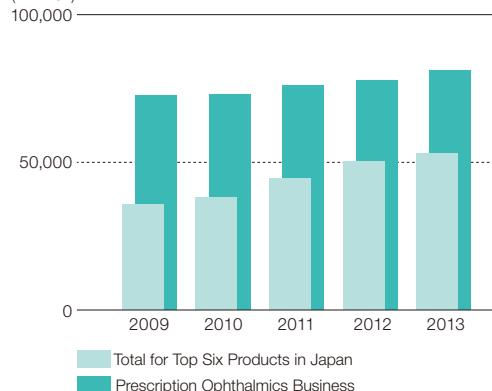
Sales Trends for the Top Six Products in Japan

(¥ Million)



Sales of Top Six Products in Japan in the Prescription Ophthalmics Business

(¥ Million)



## Treatments for Corneal and Conjunctival Epithelial Disorders

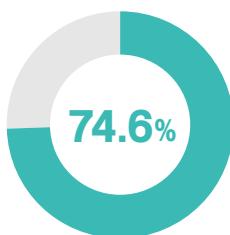
### Market Trends

The market for corneal and conjunctival epithelial disorder treatments associated with dry eye expanded 11.3%, to ¥39,654 million, in fiscal 2012. Dry eye is a disorder caused by inadequate tear fluid volume or a change in tear fluid composition that can result in corneal damage. Proper treatment is dependent upon proper diagnosis through regular consultations with an ophthalmologist. As this disorder is not widely recognized, many patients with obvious symptoms do not consult a doctor. In addition, the number of people suffering from dry eye is trending upward with increased use of PCs, smartphones and tablet PCs, increased use of contact lenses and the aging of Japan's population. Based on the aforementioned, the market for corneal and conjunctival epithelial disorder treatments is expected to continue growing.

### Operating Results

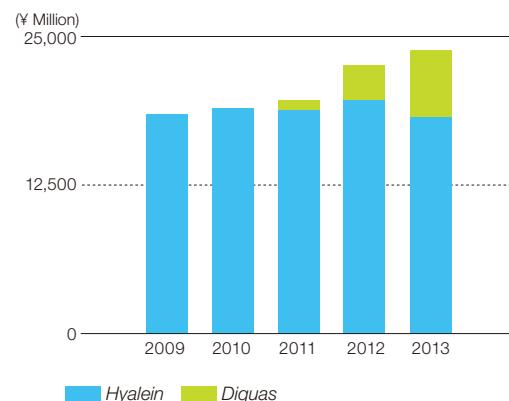
In fiscal 2012, sales of *Hyalein*, a mainstay Santen product, decreased 7.2%, to ¥18,274 million, due to the impact of NHI drug price revisions. This was despite the product's attributes, which help improve patients' quality of life (QOL), and Santen's aggressive dry eye awareness campaign targeting patients and medical professionals. Sales of *Diquas*, which was launched in December 2010, grew sharply by 95.5%, to ¥5,563 million. Santen maintained a firm 74.6% share of the corneal and conjunctival epithelial disorder treatment market. This market share was attributable to Santen providing more options for treating dry eye, for which there are high unmet medical needs.

Santen plans to continue promoting a greater understanding toward the diagnosis and treatment of dry eye to further raise awareness. In strongly advocating that new patients—there are estimated to be at least 8 million in Japan alone—and existing patients consult their doctors to receive proper and continuous treatment, Santen will link efforts to further enhance awareness toward the treatment of dry eye with aims to strengthen the Company's presence and standing further within the corneal and conjunctival epithelial disorder field.



Treatments for Corneal and Conjunctival Epithelial Disorders  
Market Share

### Sales of *Hyalein* and *Diquas*



#### *Hyalein* (Launched in 1995)

*Hyalein* was Japan's first corneal and conjunctival epithelial disorder treatment. It is a highly water-retentive ophthalmic solution that increases tear film stability. *Hyalein* accelerates corneal epithelial bonding and migration, which in turn helps repair corneal epithelial damage. It is generally used as a treatment for damage to the eye caused by dry eye, eye surgery, contact lens use or Sjögren's syndrome<sup>1</sup>.



1. An auto-immune disease characterized mainly by a general dryness, especially of the eyes and mouth. Middle-aged and elderly women are particularly prone to this disease.

#### *Diquas* (Launched in 2010)

*Diquas* is the first approved P2Y<sub>2</sub> receptor agonist in the world to be formulated as an ophthalmic pharmaceutical and has a new mechanism of action for the treatment of dry eye. *Diquas* promotes the secretion of mucin<sup>2</sup> and tear fluid, helping to heal damage to the ocular surface by improving the condition of tears.



2. The surface of the cornea contains an aqueous layer and a mucin layer containing complex glycoproteins. Loss of mucin makes it easier for the tear film covering the surface of the eye to break up, which can be a cause of dry eye.

Moving forward, as a leader in the dry eye market in Japan, Santen will continue to actively bolster its product lineup and bring new additional treatment methods to market that address the needs of patients and medical professionals.

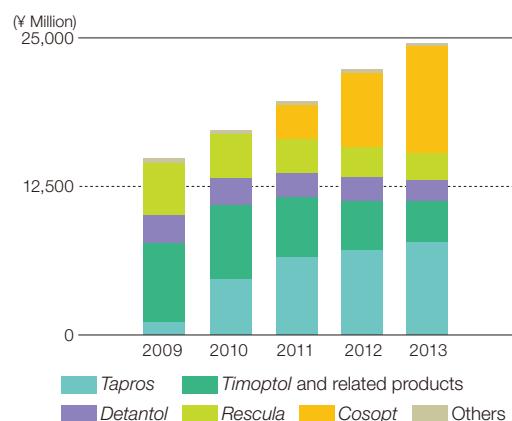
## [Domestic Operations]

### Treatments for Glaucoma

#### Market Trends

The glaucoma treatment market grew 2.8%, to ¥94,772 million. Treatments for glaucoma represent the largest segment of Japan's prescription ophthalmic pharmaceutical market, accounting for approximately 35% of the total. Increased intraocular pressure is a significant risk factor resulting in damage to the optic nerve. This can lead to visual field loss and in some cases blindness. Glaucoma is the most common cause of blindness in people with ophthalmic disease in Japan. According to epidemiological studies, there are a large number of individuals with glaucoma who have not been diagnosed by doctors. A key issue remains early detection and treatment of this disorder. The glaucoma market is expected to expand going forward, mainly due to the increase in patient numbers owing to population aging.

#### Sales of Treatments for Glaucoma



#### *Tapros* (Launched in 2008)

*Tapros* is a prostaglandin-related treatment with strong intraocular pressure-reduction properties. It is the first product of its kind to undergo clinical trials as a treatment for normal tension glaucoma, the most common glaucoma disorder among Japanese people.



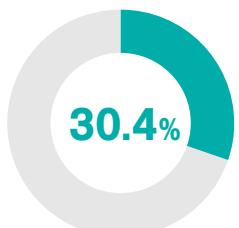
#### *Cosopt* (Launched in 2010)

*Cosopt* is a leading treatment for glaucoma that combines dorzolamide hydrochloride and timolol maleate, delivering a significant reduction in ocular pressure in a single agent.



### Operating Results

In December 2008, Santen introduced *Tapros*, which meets the treatment needs of patients with glaucoma and ocular hypertension. Reflecting steady market penetration, *Tapros* sales grew 5.9% year on year in fiscal 2012, to ¥7,605 million. In June 2010, Santen launched *Cosopt Combination Ophthalmic Solution*. Sales of this product have also climbed steadily to reach ¥9,007 million, and the Company's share of the glaucoma treatment market improved to 30.4% in fiscal 2012, as Santen maintained the top market share.



Treatments for Glaucoma Market Share

In fiscal 2013, Santen will push ahead with efforts to maximize the market value and achieve greater market penetration of mainstay products *Tapros* and *Cosopt Combination Ophthalmic Solution*. This includes *Tapros Mini*, a new preservative-free, unit-dose, single-use formulation for which Santen has received manufacturing and marketing approval. Santen will also continue to highlight the particular benefits of *Rescula* and *Detantol*, while upgrading and expanding its product lineup in the glaucoma field. Looking ahead, we will increase our presence in the glaucoma market by actively providing the latest glaucoma-related information and advice on prescribing pharmaceuticals as well as medical information that meets the needs of medical professionals.

### Anti-Infective Ophthalmics

#### Market Trends

The overall scale of the anti-infective ophthalmic market contracted 11.9%, to ¥18,907 million, continuing the declining trend over recent years. One reason is the shortening of the duration of treatment for anti-infective ophthalmic products after cataract and other ocular surgeries.

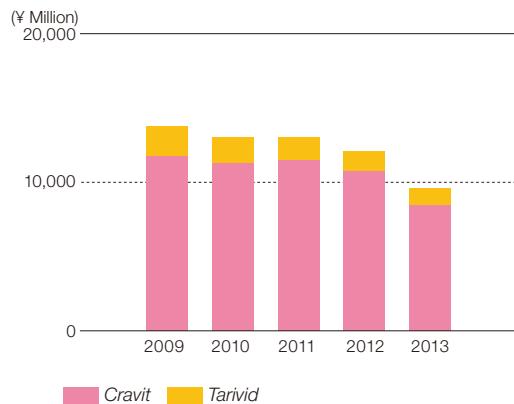
### Operating Results

In fiscal 2012, sales of the Company's two key products, *Cravit* and *Tarivid*, declined 20.8% year on year, to ¥9,585 million, due to the market's contraction and the impact of competitor products. Santen's share of the anti-infective ophthalmic market fell to 61.6% year on year. However, the Company continues to maintain a dominant position in this market.



Anti-Infective Ophthalmics Market Share

### Sales of Cravit and Tarivid



#### Cravit (Launched in 2000)

Cravit is a fluoroquinolone antibacterial agent. Its active ingredient, levofloxacin, is an optically active isomer of ofloxacin, the active ingredient of Tarivid Ophthalmic Solution. Cravit offers strong antibacterial properties and intraocular penetration.



#### Tarivid (Launched in 1987)

Tarivid is the world's first fluoroquinolone anti-infective ophthalmic pharmaceutical. It is a synthetic antibacterial drug containing the active ingredient ofloxacin that was developed by Daiichi Sankyo Company, Limited. With a broad spectrum coverage, Tarivid Ophthalmic Solution displays strong antibacterial activity.



In June 2011, amid strong demand for higher concentration anti-infective ophthalmic pharmaceuticals in step with advances in pharmacokinetics research, Santen launched the higher concentration Cravit Ophthalmic Solution 1.5%, which leverages the high solubility of levofloxacin. Clinical trials have confirmed significant efficacy. Cravit Ophthalmic Solution 1.5% has won high marks in clinical settings since its launch for the early dissipation of major symptoms.

## Anti-Allergy Ophthalmics

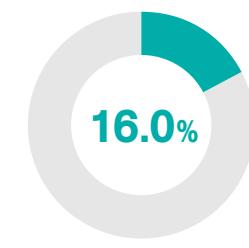
### Market Trends

In fiscal 2012, the anti-allergy ophthalmic pharmaceutical market increased 16.8%, to ¥30,884 million. This was mainly attributable to cedar pollen levels, a major cause of allergic conjunctivitis, which were higher in Japan during the fiscal year under review.

### Operating Results

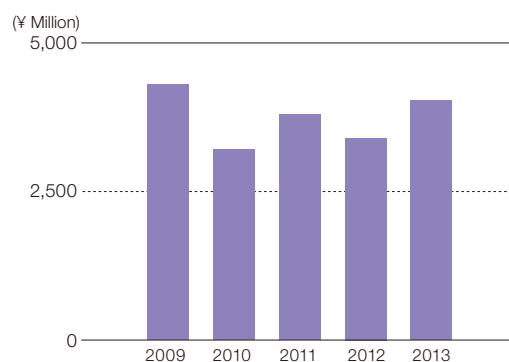
In fiscal 2012, Santen focused on providing information on its products as well as allergic disorders. Sales of Livostin increased 20.6%, to ¥4,036 million. Santen's share of the anti-allergy ophthalmic pharmaceutical market was 16.0%, as the Company maintained a certain market presence.

Livostin provides rapid relief from year-round and seasonal allergy symptoms such as itching and redness and thus contributes to an improved patient's QOL. By continuing to emphasize these product characteristics, we aim to expand both sales and market share of this product.



Anti-Allergy Ophthalmics Market Share

### Sales of Livostin

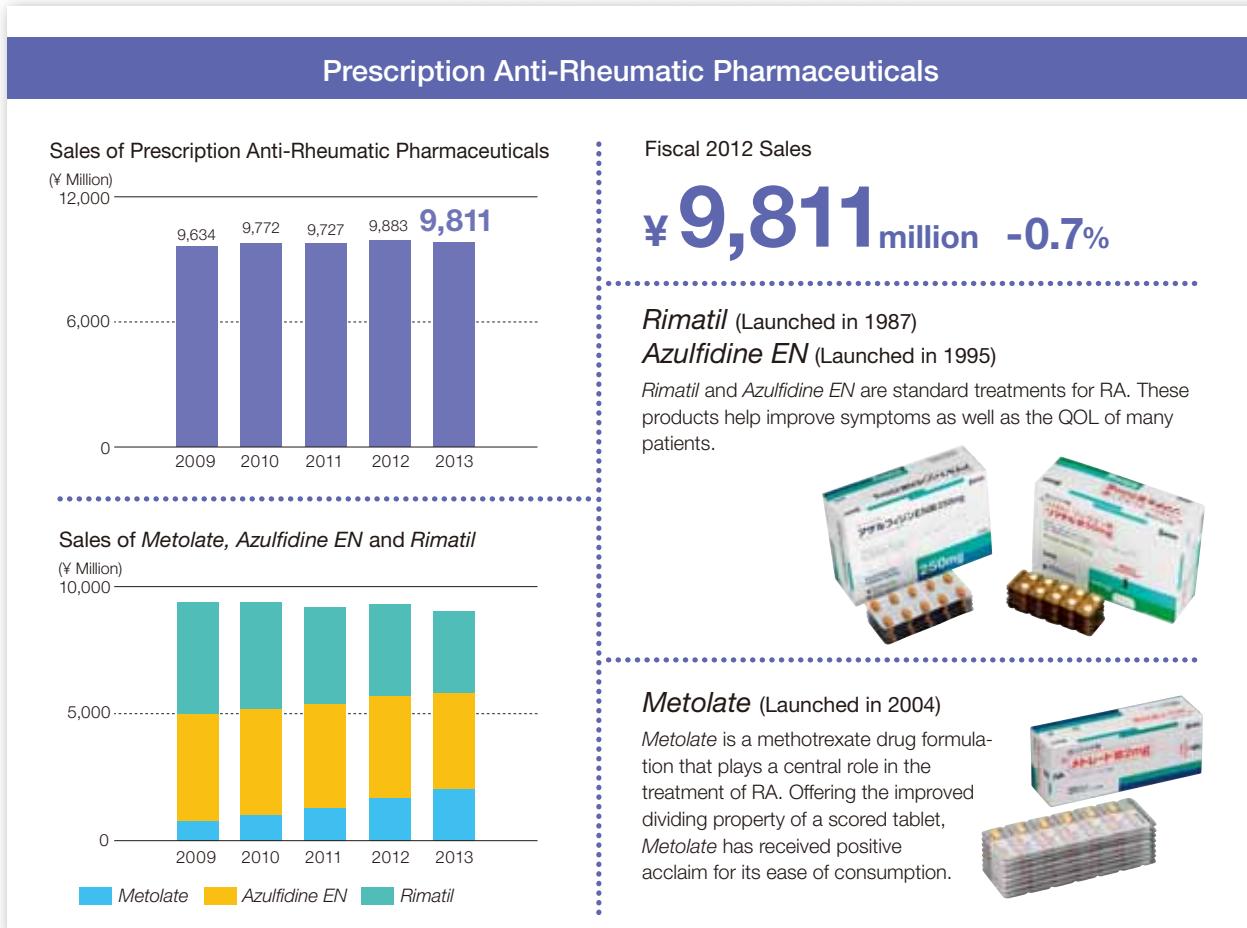


#### Livostin (Launched in 2001)

Livostin is an H<sub>1</sub> blocker ophthalmic solution that boasts high compatibility and specificity with respect to histamine H<sub>1</sub>-receptors and a long duration of antihistaminic action.



## [Domestic Operations]



### Market Trends

The Japanese market for disease-modifying anti-rheumatic drugs (DMARDs)<sup>1</sup> expanded slightly year on year, to ¥27,260 million. Although the causes of rheumatoid arthritis (RA) are yet to be fully identified, it has the appearance of an immune disorder that causes inflammation in the joints and pain and swelling. It can also lead to bone and cartilage damage and subsequent joint deformity. It is estimated that there are approximately 700,000 people with RA in Japan today. The number of RA patients is expected to rise in the future in line with the nation's aging population. The overall size of the market is also projected to increase for this reason.

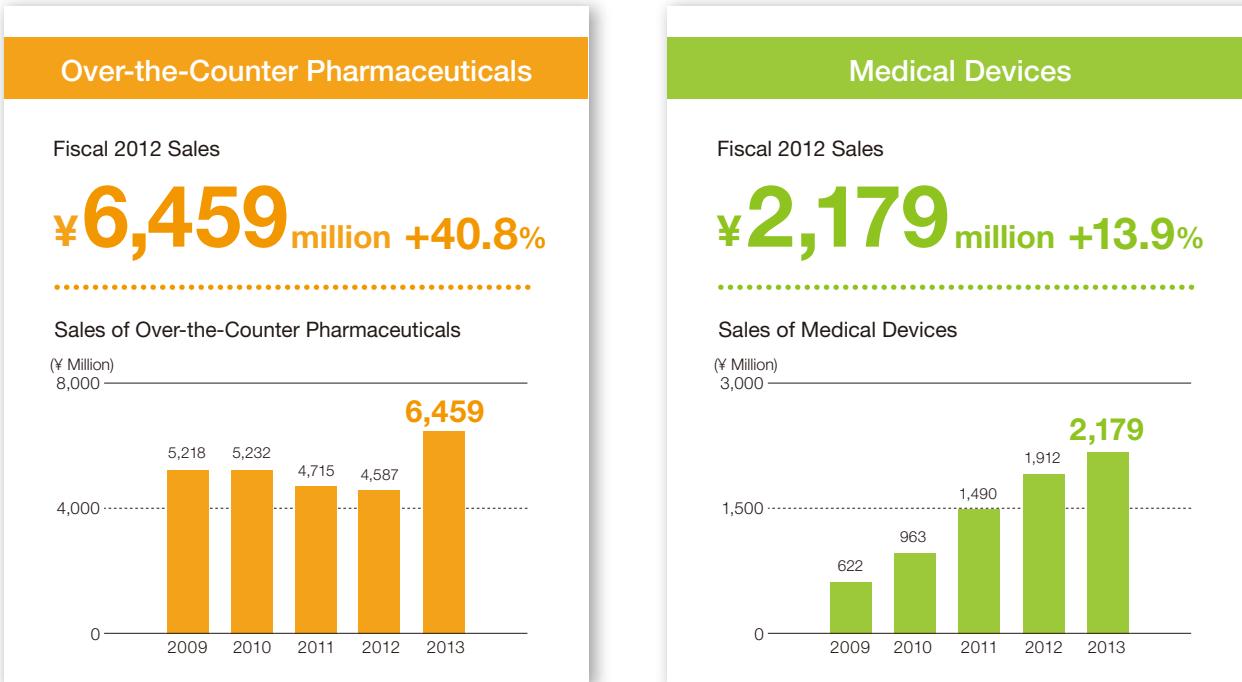
1. A class of medicines that are used not only to alleviate symptoms but also to treat the causes of disease. The anti-rheumatic effect works by calming inflammation through the correction of immune abnormalities, which are considered a cause of RA.

### Operating Results

In fiscal 2012, sales of mainstay *Rimatil* and *Azulfidine EN* declined 10.7% and 6.5%, respectively, compared with the previous fiscal year, partly due to the impact of NHI drug price revisions. However, sales of *Metolate*, a product which continues to make steady inroads in the market since its

launch in July 2004, registered another year of sharp growth, climbing 19.6%. Overall, sales of prescription anti-rheumatic pharmaceuticals edged down 0.7%, to ¥9,811 million. Santen continues to maintain its position as leader of the traditional DMARDs market, excluding biological drugs (biologics), with a 39.7% share.

The introduction of biologics has brought about a significant change in the market environment for RA treatments. The treatment goal has now become achieving remission close to a cure. However, this goal cannot be achieved only with biologics, meaning that traditional DMARDs have an important role to play. *Rimatil* and *Azulfidine EN* are the first-choice drugs for the early treatment of RA, and are used in combination with methotrexate drug formulations and as a controller medication for low disease activity. Meanwhile, *Metolate* is a first-choice drug for patients with high activity and plays a central role in treating rheumatism. Santen will therefore work hard to achieve greater penetration of these three drugs, so as to contribute to even higher QOL for patients.



## Market Trends

In fiscal 2012, the OTC pharmaceuticals market expanded slightly year on year, with demand for ophthalmic solutions rising among consumers with various eye trouble caused by increased pollen dispersal and other factors.

## Operating Results

The Company's OTC business is centered on a range of ophthalmic products, including the *Sante FX* series, one of Japan's top-selling ophthalmic solution brands, and the *Sante 40* series, which is highly effective in improving blurred vision. In fiscal 2012, OTC pharmaceutical sales rose sharply by 40.8%, to ¥6,459 million, highlighting the success of promotional activities for the *Sante Medical* series and a tie-up campaign with an Evangelion anime movie for *Sante FX*. This result also reflected the addition to the OTC pharmaceutical lineup of *Soft Santear*, an artificial tears eye drop that was sold under the prescription pharmaceuticals category through the previous fiscal year. With fierce competition set to continue in the market, Santen will focus on carving out new markets and growing sales with the launch of new products such as *Sante Beautéye* and *Sante PC*.



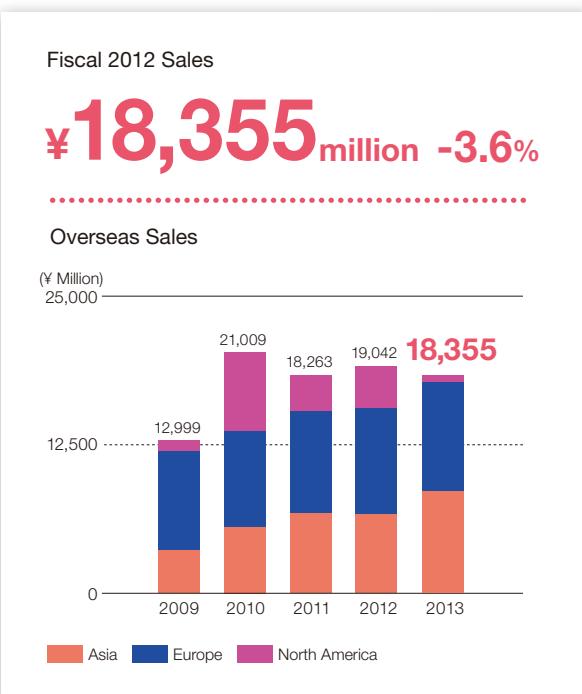
## Market Trends

Santen's medical device business specializes in intraocular lenses (IOLs) in the cataract surgery field. In recent years, demand for IOLs has shifted primarily to foldable lenses that can be inserted through a small incision.

## Operating Results

Since 2008, Santen has been selling the *Eternity* series of foldable IOLs, which are made of a new glistening-free hydrophobic acrylic material manufactured by Advanced Vision Science, Inc., a U.S. subsidiary of Santen. Thereafter, Santen has worked to enhance its lineup of products. In 2009, the Company launched *Eternity Natural*, a colored IOL that is expected to offer more natural color vision. Then in 2011, Santen launched *Accuject*, an injector that achieves a smaller incision size. In January 2013, the Company launched *Eternity Natural Uni*, a novel single piece IOL with an original aspheric design. Thanks to greater market penetration based on product development aimed at making surgery easier for physicians and patients, sales of medical devices were up 13.9%, to ¥2,179 million. Santen will continue efforts to enhance the market penetration of the *Eternity* series, taking advantage of the product concept, "high-quality IOL with outstanding transparency," and thereby increase sales of medical devices.

## [Overseas Operations]



### Steady Growth in the Regions in Which Tafluprost Is Sold

Currently, Santen directly markets tafluprost in 29 countries worldwide including Japan. The Company has granted tafluprost sales rights in certain countries under a licensing agreement with Merck & Co., Inc. Together with sales by Merck & Co., tafluprost is sold in more than 60 countries around the globe (as of August 6, 2013).



Aiming to become a specialized pharmaceutical company with a global presence, Santen is accelerating the development of overseas operations. In Europe, Santen grew sales of its new treatment for glaucoma and ocular hypertension, *Taflotan* (tafluprost, sold as *Tapros* in Japan) as an earnings driver, particularly in Eastern Europe and Germany. In Asia, Santen grew sales in China, while in Korea Santen successfully increased its market share. On a yen basis, overseas sales of prescription ophthalmic pharmaceuticals increased 12.5%, to ¥17,856 million.

Overall, overseas sales declined 3.6% to ¥18,355 million, due to a decrease in one-time payments included in revenues derived from product and technology licensing agreements with U.S.-based companies Merck & Co., Inc. and Bausch & Lomb Inc.

### Europe

The European market for prescription ophthalmic pharmaceuticals has been growing at an annual rate of approximately 10% (monetary basis), supported by a combination of rising numbers of patients diagnosed with glaucoma and dry eye syndrome as well as increasing economic prosperity in Eastern Europe and Russia. At the same time, the European market is characterized by its diversity—each country in the region has a different health insurance system and different medical treatment practices. Under these circumstances, the Company is engaging in sales and marketing activities that capture the specific characteristics of each country.

Santen is advancing its sales and marketing activities in 34 European countries, including Russia, Germany and countries in Northern and Eastern Europe. The anti-infective ophthalmic solution *Oftaquiz* (levofloxacin, sold as *Cravit* in Japan) has gained an excellent reputation for preventing and healing eye infections and is now available in 29 countries. Additionally, Santen has already obtained approval for *Taflotan*, a treatment for glaucoma and ocular hypertension, in at least 40 countries throughout Europe. Currently, we market this product directly in 23 countries including Germany. In Western Europe (except Germany), an area in which Santen does not have a sales platform, we have granted sales rights for tafluprost to Merck & Co., Inc.; tafluprost is sold in at least 10 countries in Europe under this agreement.

The Company's subsidiary in Finland, Santen Oy, manufactures pharmaceuticals for the European and the U.S. markets at its Tampere Plant, and is one of Santen's global R&D bases.

### North America

In the U.S., marketing has begun for glaucoma and ocular hypertension treatment tafluprost under a licensing agreement with Merck & Co., Inc. On the device side, Santen granted worldwide rights, excluding Japan, for the development, manufacture and marketing of the *Eternity IOL* product and its materials to Bausch & Lomb Inc. in March 2009.

### Asia

The Company's vision for the Asian market is to become the top specialized ophthalmic pharmaceutical company. Accordingly, Santen is striving to enhance long-term relationships with patients and medical professionals, thereby contributing to the improvement of ophthalmic treatment in the region. Santen is conducting business in

China, Korea and the ASEAN nations guided by this vision.

Santen began exporting to China, which is driving growth in Asia, in the 1980s and since then has established the Santen brand in this market. In 2005, the Company established Santen Pharmaceutical (China) Co., Ltd., which commenced operations at the Suzhou Plant in 2008 and began marketing using its own MRs in 2009. Santen Pharmaceutical (China) is extending its operations from China's major metropolitan cities to major outlying cities. Through these activities, the company is providing pharmaceutical information. Santen Pharmaceutical (China) sells prescription ophthalmic pharmaceutical products including *Cravit* (levofloxacin), anti-infective eye drops, and *Hyalein* (sodium hyaluronate), a corneal and conjunctival epithelial disorder treatment. Also, Santen is working to increase market awareness and penetration of the Santen brand in the Korean and ASEAN markets through Santen Pharmaceutical Korea Co., Ltd. in conjunction with local distributors and agents. In May 2010, *Taflotan*, a glaucoma and ocular hypertension treatment, was launched in Korea, and at the

Santen's Annual Growth Rate  
in the Chinese Market in Fiscal 2012

\*Excluding special factors

Approx. **20%**

same time, Santen commenced direct marketing through Santen Pharmaceutical Korea and is providing pharmaceutical information on ophthalmic disease through its own MRs. In 2012, approval was obtained for integrated production operations covering everything from formulation and filling through packaging at the Suzhou Plant. At the same time, preparations are underway for the establishment of a new sales and marketing subsidiary, as work continues to expand the range of products handled.

## TOPICS | Business Development in China

### Integrated Production Launched in China with the Aim of Being No.1 in Asia

In July 2012, Santen Pharmaceutical (China)'s Suzhou Plant obtained approval to conduct integrated production operations covering everything from formulation and filling through packaging. This approval means that the plant is now able to more quickly respond to customer needs with a system that can perform all functions from product development and production through sales and marketing in China. Santen continues to build a highly competitive globalized product supply system based on optimal usage and rationalization of global production capabilities. Integrated production at the Suzhou Plant is viewed as a major step toward being No.1 in Asia, not just in the Chinese market.

China's government is focusing on nurturing high-value-added and R&D-oriented industries. In the pharmaceutical industry, China tightened regulations in 2011, requiring much higher standards in terms of production and quality assurance. The Suzhou Plant obtained government approval for pharmaceutical production operations compliant with new GMP<sup>1</sup> by harnessing the technologies and expertise Santen has amassed at its plants in Japan.



At present, the plant is involved with the integrated production of the anti-infective ophthalmic *Tarivid* (ofloxacin), one of Santen's mainstay products, in China. In the future, however, it aims to produce and supply various products that match medical needs in China by exploiting its potential as a world-class production base.

1. Good Manufacturing Practice: Standards relating to pharmaceutical production management and quality control

# Corporate Social Responsibility (CSR)

# CSR

## Guided by Santen's Values

—“*Tenki ni sanyo suru*”—

Santen continues to help enrich the quality of life (QOL) of patients around the world through the provision of outstanding products and services via its business activities.



## CSR Integrated into Business Conduct

Santen's Values—“*Tenki ni sanyo suru*”—embody what the Company has continued to recognize as important over 120 years since its foundation in 1890. Our mission is to benefit patients and their loved ones, and thereby contribute to society, by always pursuing creation and innovation.

To ensure that all business activities are consistent with our company values and mission, we have established “Organizational Principles” to articulate the ideal state of our organization and “Individual Action Principles” to guide how employees should act and behave. To provide more specific action guidelines, we also formulated the “Santen Code of Practice,” which comprises “Corporate Action Declaration” and “Code of Conduct.” Focusing on the three pillars of “customer trust,” “employee responsibility and growth” and “harmony with society,” Santen Code of Practice requires employees not only to comply with all applicable laws and regulations, but also to observe the highest standards of ethics and integrity in their conduct. We work to disseminate and promote adherence to Santen Code of Practice throughout the Group.

As its long-term strategic vision for 2020, Santen aims to be a specialized pharmaceutical company with a global presence. To achieve this aim, Santen formulated the Fiscal 2011-2013 Medium-Term Management Plan, which is guiding the development of business activities. Our basic policy is to continue contributing to the improvement of QOL (Quality of Life) of patients around the world by providing appropriate products and services and conducting business activities consistent with Santen's Values.

We believe that by conducting business activities and CSR activities in an integrated and continuous manner, we can contribute to a sustainable society and environment, leading to the realization of our long-term strategic vision.

## Core Fields for CSR Promotion

In April 2011, Santen established the CSR Division, which formulated proprietary core fields for CSR promotion based in part on the approach of ISO 26000<sup>1</sup>, the international standard for social responsibility. Over the next few years, Santen will work to raise the CSR awareness of all Santen Group employees by expanding and enhancing its CSR management system.

Furthermore, Santen receives various opinions from the dialogue it conducts with stakeholders defined in the core fields for CSR promotion. Santen believes that it is important to use evaluations of its CSR activities in examining how future activities should be implemented in order to raise the level of those activities.

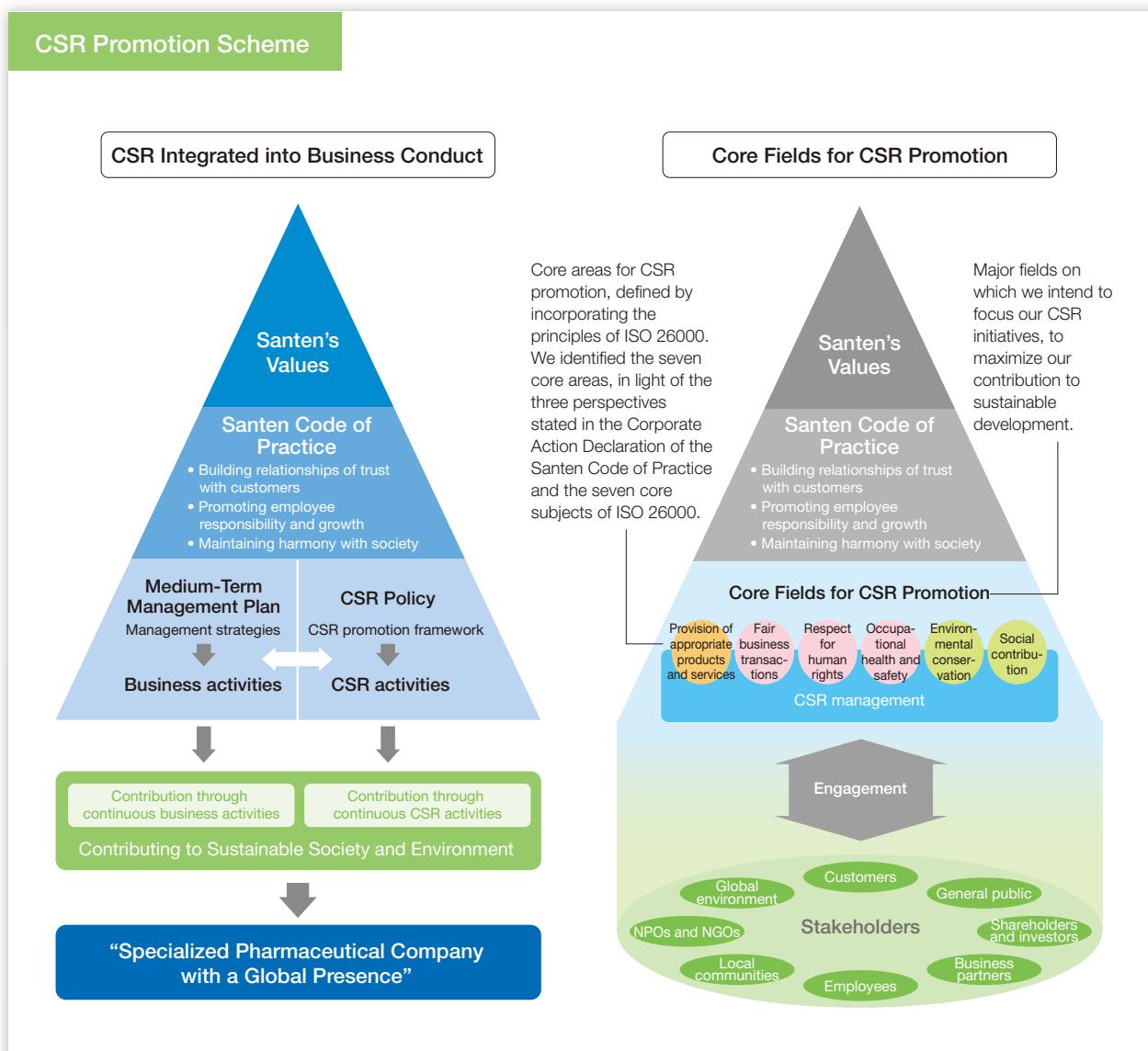
1. ISO 26000 was issued by the International Organization for Standardization (ISO) to provide guidance on social responsibility. It is applicable not only to corporations but also to all organizations, including governments, schools, and NGOs.

## CSR Management

In order to promote specific CSR activities, the Santen Group considers it essential to integrate CSR into its management strategies, and to practice CSR as part of its business operations. In line with this, on the basis of Santen's Values and the three perspectives of "customers," "employees" and "society" stated in the Santen Code of Practice, as well as the core subjects of ISO 26000, we defined core fields for CSR promotion, for each of which basic policy has been laid down. We also developed a conceptual framework for CSR initiatives that gives an overview of the CSR issues that we will address.

For each of the seven core fields of CSR promotion, we have defined medium-term activity themes and specific

action items to be carried out. In implementing the medium-term activity themes and action items, we will operate the Plan-Do-Check-Act (PDCA) cycle both in the short -and medium-term time frame. And through close analysis of the issues and areas requiring improvement identified through the PDCA cycle, we will define key performance indicators (KPIs) as soon as possible to further promote and strengthen our CSR management.



## Building Relationships of Trust with Customers

### Provision of Appropriate Products and Services

#### Developing and Providing Outstanding Products

The Quality Compliance Division is deeply involved in such wide-ranging processes as product research and development, manufacture and sales. In addition to adhering to the Pharmaceutical Affairs Law in Japan, which stipulates strict standards governing pharmaceutical quality control and post-marketing safety supervision, Santen has established a world-class quality assurance system based on its own specifications and standards.

From a manufacturing perspective, Santen maintains a domestic plant network encompassing Noto and Shiga. Overseas, the Company operates plants in Tampere in Finland and Suzhou in China. Collectively, this represents a structure that ensures the stable manufacture of approximately 300 million bottles per year of ophthalmic solutions to patients worldwide.

#### Providing Information and Services Related to Products and Disorders

Providing medical professionals with information about indications, side effects, and methods of use is essential to ensuring the safe and correct use of products. Santen accordingly has a sales force of MRs across Japan who provide accurate information in a timely manner. In order to maintain and enhance the quality of this flow of information, we continuously update MR training with specialized education.

Our Customer Service Center deals comprehensively with customer inquiries on a centralized basis, and we channel customer feedback to the product development process to improve our products and enhance our information services.

We also disseminate information through our websites to the public and medical professionals about eye diseases, the correct usage of ophthalmic solutions, rheumatoid arthritis, and pharmaceuticals and medical devices.



The Company's website was recently revamped. <http://www.santen.com/>

## Promoting Employee Responsibility and Growth

### Fair Business Transactions

Santen has revised its information security measures to foster compliance awareness among employees and works to rigorously enforce personal information protection.

Santen recognizes that ensuring compliance in business activities is also an important issue. As such, Santen works to build sound and constructive relationships with business partners, and at the same time properly operates and refines its internal control system.

### Respect for Human Rights

Santen has formulated a policy on human rights education and an action plan, as well as promoting human rights awareness. Specifically, we work to foster an awareness of respect for human rights through training based on rank and position within ordinary training programs, the issuance of news related to human rights, solicitation of human rights slogans and other actions.

We are also promoting the employment of people with disabilities. In 1997, we established Claire Co., Ltd., a specified subsidiary, for this purpose. In order to provide a workplace in which people with disabilities can work with vigor and enthusiasm, we consistently improve conditions while encouraging the development of competencies.

### Occupational Health and Safety

Based on its CSR policy concerning occupational health and safety, Santen operates a related management system and implements various measures at Head Office, the Noto Plant, the Shiga Product Supply Center, and the Nara Research and Development Center in order to maintain a safe, clean and comfortable workplace environment while promoting improved employee health.



MR's information provision activities

## Maintaining Harmony with Society

### Environmental Conservation

Santen sees preservation of nature and the conducting of environmental conservation activities as important management issues based on the theme of handing down a beautiful earth to future generations. As an organization, Santen engages in various environmental issues such as preserving biodiversity in order to contribute to the creation of a low-carbon society and a recycling-oriented society. At the same time, Santen employees engage in voluntary activities to conserve the environment. Furthermore, Santen has built an environmental conservation system that is integrated with business activities, and under this system promotes activities to reduce its environmental load and conserve the natural environment. All plants in Japan and overseas subsidiary Santen Oy have obtained ISO 14001 environmental management system certification.

Santen assesses its impact on the environment in terms of inputs and outputs. The former refers to the input of energy, materials and water resources associated with business activities, while the latter refers to emissions into the air and water of industrial waste. Furthermore, Santen assesses costs related to environmental conservation measures (investments and expenses) and benefits (economic and environmental preservation effects) with reference to the Environmental Accounting Guideline (2005) issued by the Ministry of the Environment and continuously implements measures to reduce its environmental load.

### Social Contribution

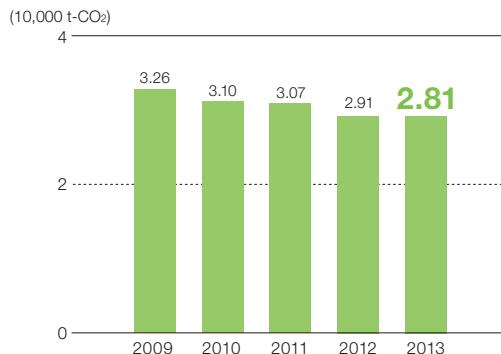
Santen engages in social contribution activities centered on medical care and welfare connected with its business domains and on local communities.

In the medical care and welfare fields, Santen continuously donates to a number of organizations including Helen Keller International, an NGO that is devoted to fighting and treating



At a voluntary training session at Claire

#### CO<sub>2</sub> Emission Volumes



preventable blindness in developing countries, as well as the Japan Eye Bank Association and the Japan National Society for the Prevention of Blindness. Furthermore, a joint lecture program was formed with the Nara Institute of Science and Technology to develop personnel who will advance leading-edge science and technology in the future. In this program, researchers from the Nara Research and Development Center instruct students at research facilities. We also support the Chinese Ophthalmology Scholarship Program in China and the Ophthalmology Training Fund in Korea in support of the education of ophthalmologists.

In addition, Santen contributes to local communities through concerted efforts to beautify and promote the greening of the areas surrounding its headquarters, research facilities, manufacturing plants, and other main business sites while actively participating in crime prevention campaigns.

We also make donations, provide free supplies of pharmaceuticals and other items, and engage in other activities as a corporate citizen in response to relief efforts for large-scale disasters.



A solar power generation system at the Nara Research and Development Center

For more detailed information, please read our CSR Report in Japanese or Environmental Data Book in English on our website.

Japanese: <http://www.santen.co.jp/> English: <http://www.santen.com/>

# Corporate Governance

## Basic Policy

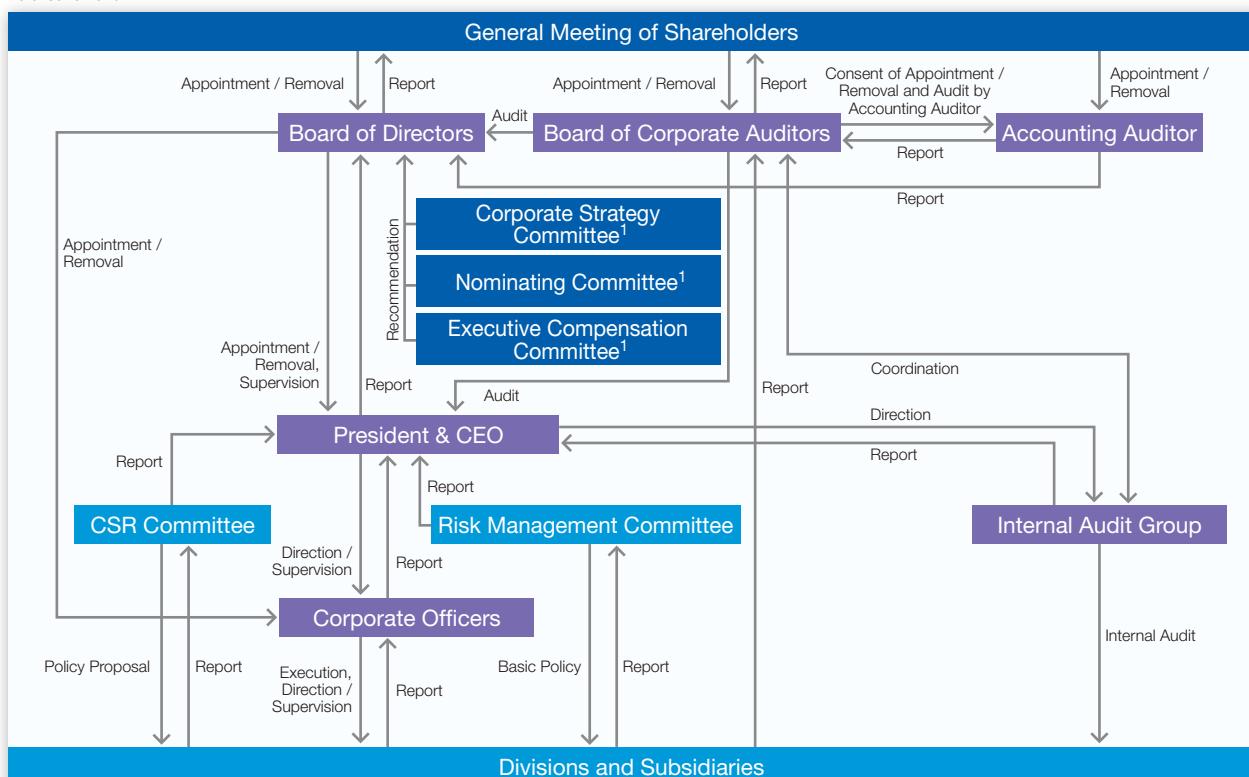
Santen recognizes that it is vital to upgrade and strengthen corporate governance systems in order to achieve and enhance corporate value, and thus returns to shareholders. Accordingly, Santen is working to raise business performance while maintaining transparent and sound management practices through the development of effective corporate governance systems.

Santen has already taken some specific steps such as appointing several outside directors to strengthen management supervision; establishing the Corporate Strategy Committee, the Nominating Committee and the Executive Compensation Committee, which are all voluntary committees made up of inside and outside directors; and introducing a corporate officer system to strengthen management and improve the speed of business execution. Santen will continue to strengthen corporate governance further going forward to improve management transparency and objectivity.

The Santen Group has adopted a governance system using corporate auditors. Santen will continue to further heighten the effectiveness and efficiency of this auditing system in collaboration with the Internal Audit Group.

## Santen Internal Governance System

As of June 2013



1. These committees are voluntary and not part of any statutory "Company with Committees" system under the Japanese Companies Act.

## Governance Systems

### Board of Directors

In addition to various statutory functions, the Board of Directors formulates management policies, strategies, and business plans for Santen. The Board of Directors makes decisions relating to the acquisition or disposal of major financial assets and important organizational or personnel-related matters, as well as oversees the execution of business at Santen and its subsidiaries. The board convenes once a month in principle. As of June 2013, the board comprised five members including three outside directors. The Board of Directors convened 10 times during fiscal 2012.

### Board of Corporate Auditors

The Board of Corporate Auditors consists of four members, including three outside corporate auditors. Corporate auditors formulate auditing policies and plans as well as attend meetings of the board of directors and other important business meetings. In addition, corporate auditors oversee the execution of duties by directors through auditing the operational and financial status of Santen's headquarters, major operating sites, and subsidiaries. The Board of Corporate Auditors convened 10 times during fiscal 2012.

## ■ Voluntary Committees

Santen has established the following three committees composed of inside and outside directors as deliberative bodies to further strengthen corporate governance and to improve management transparency and objectivity.

- The Corporate Strategy Committee deliberates on key strategic issues such as business strategies.
- The Nominating Committee deliberates on the selection of directors and submits recommendations to the Board of Directors as well as deliberates on the selection of corporate officers and corporate auditors and submits recommendations to the Board of Directors.
- The Executive Compensation Committee deliberates on the compensation of directors and corporate officers as well as submits recommendations to the Board of Directors.

Note that these committees are not part of any statutory "Company with Committees" system under the Japanese Companies Act.

## ■ Corporate Officer System

Santen has introduced a corporate officer system to strengthen management while improving the quality and speed of strategic decision-making processes. There were 10 corporate officers as of June 2013, excluding some serving concurrently as directors.

### Relationships between the Outside Directors and Outside Corporate Auditors and the Company

In selecting outside directors and outside corporate auditors, Santen applies the independence standards of stock exchanges in Japan, in addition to its own internal standards. Specifically, Santen specifies standards deemed to generally ensure independence in terms of relationships with the Santen Group (duties, transactions, stock holding, etc.) and decides on candidates after evaluating them in accordance with these standards.

None of the three outside directors or three outside corporate auditors are appointees from Santen's subsidiar-

ies or affiliates, major shareholders or leading business partners. Each maintains a degree of independence to avoid conflicts of interest with ordinary shareholders. Outside director Akihiro Okumura is Professor Emeritus of Keio University, with which Santen conducts joint research and has other dealings, and to which it also makes donations. However, these activities are medical related and are not related to management studies, Okumura's area of specialization.

## Compliance

### Internal Governance System

Santen benefits society through its business activities, with a particular focus on contributing to patients and their loved ones—which incorporates Santen's Values—as a company active in the pharmaceutical industry. At the same time, aiming to heighten society's recognition of our values to society and achieve sustainable growth, we are developing the following internal control systems.

Our compliance system, the Santen Code of Practice, which was formulated in December 1999 and revised in line with changing social conditions, consists of the Corporate Action Declaration and the Code of Conduct that defines strict ethical standards governing corporate activities. The Santen Code of Practice stipulates that the Company will not respond to any demands whatsoever made by antisocial forces that threaten the order and stability of civil society.

In addition, we have appointed a director and department responsible for internal governance, and established the CSR Committee to ensure rigorous compliance. Further, we maintain an internal system for compliance-related inquiries and an external helpline to an independent attorney, which enables employees to report directly any suspected compliance violations or to receive compliance-related advice.

### Directors' and Corporate Auditors' Remuneration

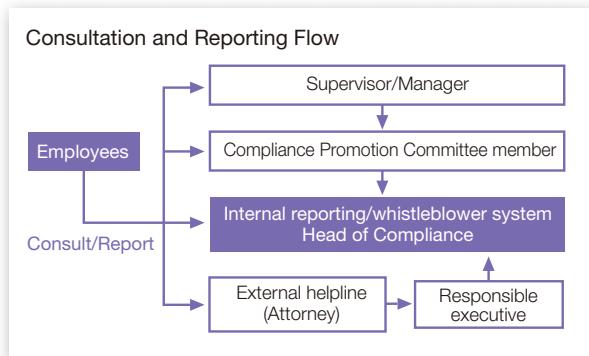
Position	Total Remuneration (Millions of yen)	Total Remuneration by Category (Millions of yen)					No. of Eligible People
		Basic Remuneration	Results-linked Remuneration	Stock Options	Bonus	Retirement Benefits	
Directors (Excl. Outside Directors)	212	59	71	29	—	52	3
Corporate Auditors (Excl. Outside Corporate Auditors)	23	23	—	—	—	—	1
Outside Directors and Outside Corporate Auditors	61	61	—	—	—	—	7

Note: As of June 2013, the retirement benefit program was abolished.

Santen aims to increase the appropriateness of Santen's operations, by building a control system in which the Company provides recommendations and guidance on increasing appropriateness, developing regulations for the control of Group companies to clarify their roles and responsibilities, and strengthening audit functions at major Group companies.

As a department independent from operating divisions, the Internal Audit Group—comprised of four people including the chief officer—verifies that the above internal control systems work efficiently. The Internal Audit Group reports directly to the president of Santen.

Regarding internal control related to the reliability of financial reports, Santen has established a system whereby divisions and principal subsidiaries check the appropriateness of their systems, while the Internal Audit Group checks the suitability of these self-checks. In fiscal 2012, Santen did not discover any significant deficiencies or omissions that could undermine the reliability of its financial reports. Santen will continue to develop and maintain systems that consistently meet the requirements of the internal control reporting system, which is based on Japan's Financial Instruments and Exchange Act.



### Internal Audits and Corporate Auditors' Audits

#### ■ Cooperation between Corporate Auditors and Accounting Auditors

The corporate auditors hold a meeting with the accounting auditors at the beginning of each fiscal year to receive presentations on the financial auditing plans for the year and any key audit-related issues as well as to exchange opinions, including requests from the corporate auditors. The accounting auditors present audit findings to the corporate auditors at meetings three times a year to exchange opinions.

In addition, the corporate auditors attend an audit review meeting with the accounting auditors after the conclusion of the quarterly and year-end audit reviews to exchange opinions on audit results and procedures.

#### ■ Cooperation between Corporate Auditors and the Internal Audit Group

Corporate auditors and the Internal Audit Group cooperate closely at all times. For instance, they hold regular meetings at which they share progress with their respective audit plans and audits, and new points to be aware of, while also simultaneously visiting business sites and subsidiaries to conduct audits as necessary.

## Risk Management

### Risk Management Promotion Framework

Santen has built a system for responding appropriately to major risks related to its business activities, which is based on a Risk Management Procedure Manual that sets out basic policies and a code of conduct for crisis management. Operating divisions and headquarters avoid or minimize risk by routinely gathering information as well as preparing risk management policies and countermeasures for their operations. Further, the Risk Evaluation Committee discusses risk management policies and countermeasures for significant risks that transcend several divisions. An emergency situation affecting Santen beyond a certain level triggers the operation of the Crisis Response Committee headed by a representative director. Based on Santen's Risk Management Procedure Manual, the committee coordinates efforts to minimize any losses or damages and ensure a quick recovery, and institutes measures to prevent a recurrence. The Company has established a permanent secretariat with designated executives to check the status of such risk management efforts from a Companywide viewpoint, while the Internal Audit Group examines them from an independent standpoint.

### Business Continuity Management

Medicines are high-priority necessities for people affected by natural disasters or other emergencies. Santen believes it is essential to maintain supplies of drugs to patients and healthcare workers in affected areas. To this end, Santen has analyzed business continuity-related risks, clarified policies and identified those areas critical to maintaining product supplies. Detailed plans have been formulated to guide the response to an emergency, including the necessary organizational actions. To ensure systems will work, business continuity and disaster preparedness planning and activities are also part of the PDCA<sup>1</sup>-based management cycle.

1. A method to facilitate the smooth management of business activities through a P (Plan), D (Do), C (Check) and A (Act) business activity cycle.

## Information Security

Regarding information control systems, Santen safely stores and controls information based on in-house rules such as for basic information security and document control. Furthermore, Santen has established personal information protection guidelines and a compliance program regarding personal information protection, which are explained to corporate officers and employees at training events. The Company also works to ensure that they are working properly.

## Information Disclosure

### Investor Relations Activities

Santen's basic policy is to work to disclose information actively and in an easy-to-understand manner, whilst

ensuring swift, accurate and fair disclosure of corporate information always taking the viewpoint of shareholders and investors. Santen holds financial results meeting presentations after the release of interim and full-year results for analysts and institutional investors, and also conducts conference calls for them after its first- and third-quarter results are announced. Furthermore, Santen visits overseas shareholders and investors to explain corporate information. Moreover, Santen conducts presentations for individual investors and other presentations of corporate information such as small meetings for a wide range of investors.

Santen's website carries a host of information, including financial results, annual reports, flash reports, data books, quarterly reports, annual securities reports, financial result meeting presentations, and materials for the general meetings of shareholders.

## Messages

### Comments on the Company's Governance

With the presence of shareholders and investors growing, Japanese companies are now compelled to further improve their governance. There are three core issues here: high regard for shareholders' interests, transparency of decision processes, and election of outside directors. I believe Santen has already addressed these issues in an effective way. Quick and proper disclosure, efforts to engage in dialogue with shareholders and investors, and a policy on shareholder returns reflect well management's stance. As to the results for fiscal 2012, the level of dividend payment and the execution of a stock repurchase are worthy of high praise, too. I have taken part in the board process as a relatively new director for just over a year now, and found discussions very open and lively. All directors and corporate auditors including outside ones actively engage themselves. I hope Santen will continue to realize its goal of increasing corporate value through the pursuit of its long-term vision as well as effective execution of its growth strategy.



Takayuki Katayama  
Outside Director

### The Importance of Transparency

Companies must have a meaning for society to exist and also achieve sustainable business growth for shareholders and other stakeholders. I believe that the effective functioning of corporate governance is a basic premise for achieving both of these imperatives. Santen selects independent directors and corporate auditors (independent outside directors and outside corporate auditors), discloses information in a timely and proper manner, and works to enhance its internal control system. In these and other ways, I think Santen is striving to raise management transparency, which supports corporate governance.

Indeed, management transparency plays an important role in ensuring the trust of investors in the market and fulfilling the company's accountability to shareholders and other stakeholders. As an outside corporate auditor, I will oversee Santen's continued efforts to work on ensuring that corporate governance and, in particular, management transparency functions properly.



Yasuaki Tsuchiya  
Outside Corporate Auditor

# Board of Directors, Corporate Auditors and Corporate Officers

As of August 2013



(Front row, from left) Akira Kurokawa, Sadatoshi Furukado, (Back row, from left) Akihiro Okumura, Noboru Kotani, Takayuki Katayama

## Directors

**Akira Kurokawa**  
President and  
Chief Executive Officer

**Sadatoshi Furukado**  
Director  
Executive Corporate Officer  
Japan Business and Human Resources  
Development, Head of Sales and Marketing  
Division, Prescription Pharmaceuticals

**Noboru Kotani**  
Outside Director

**Akihiro Okumura**  
Outside Director

**Takayuki Katayama**  
Outside Director

## Corporate Auditors

**Yoshihiro Noutsuka**  
Standing Corporate Auditor

**Yasuo Sato**  
Outside Corporate Auditor

**Yasuaki Tsuchiya**  
Outside Corporate Auditor

**Yutaka Mizuno**  
Outside Corporate Auditor



(Front row, from left) Atsutoshi Ota, Kenji Morishima, Masamichi Sato, Akihiro Tsujimura, (Back row, from left) Naveed Shams, Takeshi Ito, Kazuo Koshiji, Akio Kimura, Takashi Kaneko  
(Inset) Jyrki Liljeroos

## Corporate Officers

(Not including directors that also serve as corporate officers)

**Masamichi Sato**  
Senior Corporate Officer  
Head of Santen European Group  
President of Santen Holdings EU B.V.

**Jyrki Liljeroos**  
Corporate Officer  
President of Santen Oy

**Kenji Morishima**  
Corporate Officer  
Head of Human Resources  
Development and CSR Division

**Akihiro Tsujimura**  
Corporate Officer  
Head of Asia Division

**Atsutoshi Ota**  
Corporate Officer  
Head of Product Supply Division

**Akio Kimura**  
Corporate Officer  
Head of Quality Compliance  
Division

**Takeshi Ito**  
Corporate Officer  
Head of Prescription  
Pharmaceuticals Sales  
Department, Sales and  
Marketing Division,  
Prescription Pharmaceuticals

**Kazuo Koshiji**  
Corporate Officer  
Head of Finance &  
Administration Division

**Takashi Kaneko, M.D., Ph.D.**  
Corporate Officer  
Head of Research and Development  
Division

**Naveed Shams, M.D., Ph.D.**  
Corporate Officer  
Chief Scientific Officer  
President & CEO of Santen Inc.

# Financial Section

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# Report and Analysis of Operating Results and Financial Condition

## [OPERATING RESULTS]

### Net Sales

Santen's activities essentially encompass the pharmaceuticals and other businesses. At 98.1%, the vast majority of sales come from the pharmaceuticals segment. In fiscal 2012, ended March 31, 2013, sales from the pharmaceuticals segment rose 4.4% compared with the previous year, to ¥116,810 million. Sales from the other segment declined 12.2%, to ¥2,256 million. On this basis, total net sales for the fiscal year under review rose 4.1%, to ¥119,066 million.

#### Pharmaceuticals Business

##### Prescription Pharmaceuticals

Santen's prescription pharmaceuticals are divided into three categories: ophthalmics, anti-rheumatics and other pharmaceuticals. In fiscal 2012, sales of anti-rheumatics and other pharmaceuticals declined, but sales of ophthalmics increased. The overall result therefore was that prescription pharmaceutical sales increased 2.9%, to ¥110,336 million, representing 92.7% of consolidated net sales.

##### ■ Ophthalmics

Domestic sales of prescription ophthalmic pharmaceuticals improved 4.3%, to ¥81,125 million. This was largely attributable to successful promotional campaigns in Japan to provide individual medical facilities with scientific information tailored to their specific and changing needs.

Overseas, prescription ophthalmic pharmaceutical revenues were up 12.5%, to ¥17,856 million, after conversion to yen. In Europe, our concentration on promotional campaigns centered on providing medical and other information saw *Taflotan* (sold as *Tapros* in Japan), a new glaucoma and ocular hypertension treatment, increase its market share in Germany and elsewhere. In Asia, market penetration of the Company's products also progressed mainly in China and Korea. This was again attributable to successful promotional campaigns.

As a result, total prescription ophthalmic pharmaceutical sales increased 5.7%, to ¥98,981 million.

##### ■ Anti-Rheumatics

*Rimatil*, *Azulfidine EN* and *Metolate* are highly recommended in the Rheumatoid Arthritis Treatment Guidelines. Despite this strong recommendation, sales of anti-rheumatics declined 1.1%, to ¥9,874 million, due in part to the impact of NHI drug price revisions.

##### ■ Other Pharmaceuticals

Other pharmaceuticals includes revenues derived from technology-sharing agreements as well as contract work and manufacturing. Sales of other pharmaceuticals decreased 59.3%, to ¥1,481 million.

##### OTC Pharmaceuticals

Sales of OTC pharmaceuticals increased 40.8%, to ¥6,474 million, due to two main factors. One was the impact of higher sales of *Soft Santear*, which was sold under the prescription pharmaceuticals category through the previous fiscal year. The other factor was a focus on promotional campaigns, particularly for the *Sante FX* series and the *Sante Medical* series.

#### Other Businesses

##### Medical Devices

As a result of focusing initiatives on promotional campaigns for the *Eternity* foldable intraocular lens, which is made of a glistening-free hydrophobic acrylic optical material, sales of medical devices in Japan grew steadily. However, sales of medical devices as a whole declined 12.2% year on year, to ¥2,246 million, due to the inclusion of revenues derived from technology-sharing agreements in the previous fiscal year.

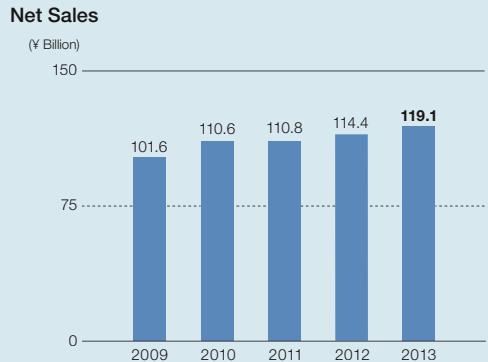
##### Others

Other sales totaling ¥10 million, down 9.6% year on year, come from the cleaning of antidust and sterilized clothing operations of consolidated subsidiary Claire Co., Ltd.

#### Net Sales by Business Segment

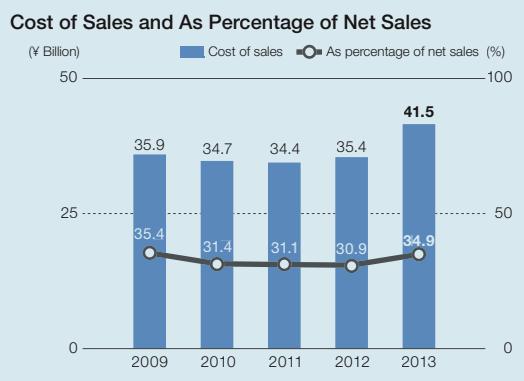
	Millions of yen		%
	2013	2012	
Pharmaceuticals Business	¥116,810	¥111,846	4.4
Prescription pharmaceuticals	110,336	107,249	2.9
Ophthalmics	98,981	93,620	5.7
Anti-rheumatics	9,874	9,987	(1.1)
Other pharmaceuticals	1,481	3,642	(59.3)
OTC pharmaceuticals	6,474	4,597	40.8
Other Businesses	2,256	2,570	(12.2)
Medical devices	2,246	2,558	(12.2)
Others	10	12	(9.6)
Total	¥119,066	¥114,416	4.1

Note: Net sales for each segment refer to sales to outside customers.



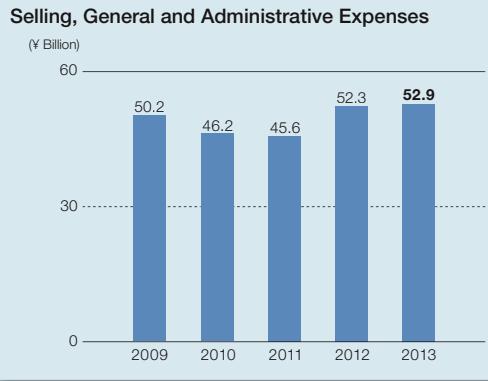
## Cost of Sales

Cost of sales increased 17.3%, to ¥41,501 million. The cost of sales as a percentage of net sales increased 4.0 percentage points, to 34.9%.



## Selling, General and Administrative Expenses

Selling, general and administrative expenses increased 1.1%, to ¥52,884 million, which included a 2.9% decrease in R&D expenditures, to ¥16,720 million.



## Operating Income

Operating income was down 7.7%, to ¥24,681 million. The operating income margin was 20.7%, down from 23.4% in the previous fiscal year.



## Other Income and Expenses

Net other income for the fiscal year ended March 31, 2013 was ¥911 million.

Other income was down ¥155 million, to ¥1,026 million. This mainly reflected a decrease in exchange gains (losses), net, and the recording of ¥57 million in gain on sale of investment securities in the previous fiscal year.

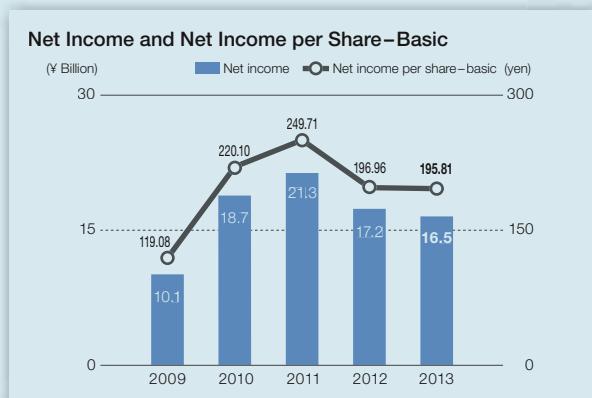
Other expenses decreased ¥7 million, to ¥115 million. This was mainly attributable to a decline in interest expense and the recording of impairment losses in the previous fiscal year.

## Income Taxes

Income taxes totaled ¥9,071 million. The effective tax rate decreased from 38.2% to 35.4%.

## Net Income

Net income was down 3.7%, to ¥16,521 million. The ratio of net income to net sales was 13.9%, down from 15.0% in the previous fiscal year. Basic net income per share was ¥195.81, down from ¥196.96, and diluted net income per share was ¥195.51, down from ¥196.76 in the previous fiscal year.

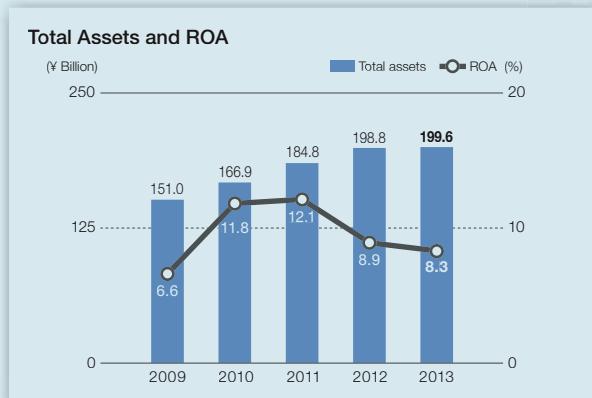


## [FINANCIAL CONDITION]

### Assets

As of March 31, 2013, total assets stood at ¥199,641 million, up ¥840 million, or 0.4%, compared with the previous fiscal year-end. While cash and cash equivalents and short-term investments decreased, accounts trade receivables and inventories increased, as did investment securities. Return on total assets (ROA) was 8.3%, down from 8.9% in the previous fiscal year.

Total current assets were ¥132,583 million, and the ratio of total current assets to total assets declined from 70.6% as of the previous fiscal year-end to 66.4%. Within total fixed assets of ¥67,058 million, net property, plant and equipment totaled ¥27,420 million, and total investments and other assets amounted to ¥39,638 million.



## Liabilities

Total liabilities as of March 31, 2013 were ¥34,509 million, up ¥569 million compared with the previous fiscal year-end. While income taxes payable declined, accounts payable and other payables increased.

Total current liabilities were ¥27,011 million, and total non-current liabilities were ¥7,498 million. Interest-bearing debt was ¥87 million, a decline of ¥28 million, or 24.5%, compared with the previous fiscal year-end.

### Net Assets

Total net assets amounted to ¥165,133 million, up ¥272 million compared with the end of the previous fiscal year. While retained earnings declined, there was an increase in foreign currency translation adjustments and an increase in unrealized gains on securities, net of taxes.

The equity ratio declined from 82.8% to 82.6%. Equity per share was ¥1,998.44, an increase of ¥110.63, or 5.9%, compared with the end of the previous fiscal year. Return on equity (ROE) decreased from 10.7% to 10.0%.

### Equity and ROE



## Capital and Liquidity

Santen strives to maintain a healthy balance sheet and to ensure an appropriate level of liquidity and sufficient resources to fund its business activities.

Cash and cash equivalents as of the end of the fiscal year under review amounted to ¥59,797 million, down ¥15,238 million compared with the previous fiscal year-end. Net cash provided by operating activities was ¥9,943 million. On the other hand, ¥4,596 million was used in investing activities and ¥21,557 million in financing activities.

## Cash Flows

Net cash provided by operating activities was ¥9,943 million, which mainly resulted from income before income taxes of ¥25,592 million, an increase in account receivables of ¥5,560 million and income taxes paid of ¥10,372 million.

Net cash used in investing activities was ¥4,596 million. While ¥4,680 million in cash was provided by proceeds from sale of short-term investments, the main outflows were ¥4,883 million for the purchase of investment securities and ¥3,609 million for capital expenditures.

Net cash used in financing activities was ¥21,557 million. The principal cash outflows were ¥13,763 million for repurchase of treasury stock, and ¥8,469 million for dividends paid.

As a result, cash and cash equivalents as of the end of the fiscal year amounted to ¥59,797 million, a decrease of ¥15,238 million.

### Cash Flows Summary

	Millions of yen		
	2013	2012	Change
Cash flows from operating activities	¥ 9,943	¥ 21,483	¥(11,540)
Cash flows from investing activities	(4,596)	(10,273)	5,677
Cash flows from financing activities	(21,557)	(8,559)	(12,998)
Cash and cash equivalents at end of year	¥ 59,797	¥ 75,035	¥(15,238)

Note: Figures in parentheses indicate a decrease.

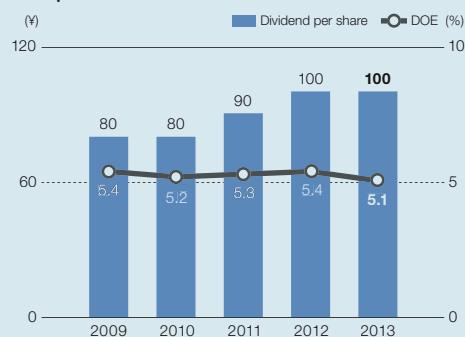
## Distribution of Profits

Santen views returns to shareholders as one of its most important management goals and has instituted the following fundamental policies for the distribution of profits:

- We will implement an appropriate dividend policy based on the Company's operating results while taking into consideration the need to secure sufficient internal reserves to fund R&D and the implementation of growth strategies for the purposes of enhancing capital efficiency and expanding corporate value.
- We will strive to increase the level of dividends in line with such factors as the Company's demand for funds and the Company's financial position.
- We will consider the repurchase and retirement of treasury stock as a flexible method of providing a return to shareholders.

To maintain a stable level of dividends, we target a dividend on equity (DOE) ratio, which combines the dividend payout ratio and ROE. Taking into consideration returns to shareholders through dividends and the improvement of capital efficiency, for fiscal 2013—the final year of the Company's Fiscal 2011–2013 Medium-Term Management Plan—our DOE target is 5.0%. On this basis, the annual dividend per share was ¥100, the same as the previous fiscal year, resulting in a DOE ratio of 5.1%.

Dividend per Share and DOE Ratio



# Risk Related to Our Business

## [FORWARD-LOOKING INFORMATION AND FACTORS THAT MIGHT AFFECT FUTURE RESULTS]

Any statements that we make, other than historical facts, contain forward-looking information based on our business plans and assumptions at the time of disclosure. Such forward-looking information includes, but is not limited to, our expected growth strategies, projected operating results, market forecasts and anticipated timing for developing, obtaining approval and bringing products to market. Our business, as well as each product we develop and market, is subject to various risks and uncertainties beyond our control. Therefore, these forward-looking statements might differ substantially from actual results. Risks and uncertainties that could affect the Company's future results and financial condition include, but are not limited to, the factors described below.

### External Factors

#### Regulatory Controls

Our prescription pharmaceutical business is subject to government regulatory controls regarding healthcare programs and drug prices in Japan and other countries. Although our current operating and/or financial projections were made in full consideration of drug price revisions in Japan to the best extent possible, those revisions that may take place beyond the scope of our anticipated projections or other revisions in healthcare programs might also affect our operating and/or financial results. In other countries and markets where we manufacture and sell our products, we continue to face a variety of regulatory controls over prices of prescription pharmaceuticals and government pressure for drug price reduction.

#### Social and Economic Conditions and Changes in the Law

Santen's future results might be affected by political and economic changes in key markets worldwide in which we operate. Our anticipated performance and financial condition might also be affected by changes in applicable accounting principles, and laws and regulations concerning taxes, the Product Liability Law, the Antitrust Law, environmental laws and regulations and other factors.

#### Foreign Exchange

Overseas sales and expenses, as well as the assets of overseas subsidiaries, affect our sales, profits and financial condition depending on foreign exchange rate fluctuations. Overseas sales for the fiscal year ended March 31, 2013 accounted for 15.4% of our consolidated net sales.

### Competitive Factors

#### Generic Products

The sale of generic products both in and outside Japan has the potential of impacting the Company's performance.

Other companies have already launched generic products in Japan for such items as *Hyalein* and *Cravit*. Looking ahead, the impact from generic products is projected to grow.

#### Dependency on Specific Products and Business Partners

##### Dependency on Mainstay Products

Total sales of *Hyalein* and *Cravit* accounted for 27% of Santen's consolidated net sales for the fiscal year ended March 31, 2013. Should any sales suspension or a decline in sales occur due to any unanticipated negative influences, such as potential product defects or newly discovered side effects, our business results and financial performance might be negatively affected.

##### Dependency on In-Licensed Products

Many products that the Santen Group sells are licensed by other companies. We hold exclusive rights to manufacture and sell ophthalmic formulations such as *Cravit*, *Detantol*, *Tapros* and *Diquas*. We also have sales rights in Japan for *Timoptol*, *Timoptol XE* and *Livostin*, and exclusive sales rights in Japan for *Cosopt*, *Azulfidine EN*, *Rescula* and *EYLEA*. Should changes be made in the terms and conditions after the expiration of such contracts or should the agreements not be renewed, our business performance might be affected.

## Dependency on Specific Business Partners

In the U.S., we have a distribution agreement with VISTA-KON Pharmaceuticals, LLC for certain prescription ophthalmics. In the event that VISTAKON cannot achieve sufficient sales of such products we consigned, our financial results might be affected.

We depend on specific business partners for the supply of certain raw materials such as the active pharmaceutical ingredient for *Cravit* and containers for our OTC pharmaceuticals. If supply of these materials is interrupted or discontinued for any reason, our pharmaceutical production might be adversely affected. Should it subsequently affect the supply of our products and cause any interruption or discontinuance, it would adversely affect our business performance.

The percentage of our business conducted with the top 10 wholesalers in Japan has reached 70% of our consolidated net sales. If our wholesale partners experience bankruptcy leading to bad debts, our business performance might be adversely affected.

## R&D Activities

### Uncertainties in New Product Development

Years are required to bring new drugs from initial R&D to final approval and marketing. Various uncertainties exist at every stage in the development process that could sidetrack a new product, such as discontinuance of development or rejection after the application is filed. It is difficult for us to accurately predict when new products, new indications or formulations under development will reach the approval stage and be ready for launch.

Forecasting a precise timeline for project development and completion depends on a number of variable factors, including, but not limited to, delayed government reviews, conflicting or unusable clinical data that does not indicate significant differences in relation to competitor products, safety and efficacy concerns and unexpected side effects—which might lead to discontinued development or delayed product launch and thereby negatively affect projected sales of new drugs.

## Potentially Insufficient Returns on R&D Investment

The creation and development of new pharmaceuticals, as well as the development of new indications and formulations, are critical for the future growth of Santen. Every year we invest significantly in R&D, and there is a possibility that future investments will not result in sales of new products sufficient to provide an adequate return.

## Issues with Alliances

Forecasts for new pharmaceuticals include various assumptions of alliances in development and/or sales. Actual results of these alliances might affect our overall sales and financial condition.

## Other Factors

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### Production Interruptions or Delays

The interruption or delay of production activities due to natural disasters or other catastrophes such as fire might affect our financial performance and condition. Certain products are only manufactured at one location. If a specific plant is forced to halt production, supply of some products might be interrupted or delayed.

### Cancellation of Sales and Product Withdrawals

If sales of certain products are cancelled, or if we withdraw products due to product quality defects, unexpected side effects, tampering or other causes, our overall financial results might be negatively affected.

### Litigation

Our main business involves the production and sales of prescription pharmaceuticals. The nature of our business makes us vulnerable to litigation related to patents, the Product Liability Law, violation of the Antitrust Law and consumer-related and environmental lawsuits. If such legal actions take place, the proceedings might affect our overall performance and financial condition. Currently, we are involved in no litigation that substantially impacts the management of the Company.

# Eleven-year Summary of Selected Financial Data

Years ended March 31

	2003	2004	2005	2006
<b>For the year:</b>				
Net sales	¥ 90,253	¥ 89,858	¥ 92,696	¥ 98,398
Cost of sales	32,272	31,859	33,710	34,535
Selling, general and administrative expenses	45,284	43,475	40,004	42,868
Operating income	12,697	14,524	18,982	20,995
Interest expense	480	366	182	94
Income before income taxes	9,947	13,775	18,436	20,342
Income taxes	1,444	7,454	7,413	7,319
Net income	8,503	6,321	11,023	13,023
Capital expenditures	7,046	3,226	4,907	2,106
Depreciation and amortization	4,311	4,521	4,750	4,824
R&D expenditures	12,719	11,853	12,620	13,971
<b>Per share data</b> (yen and U.S.dollars):				
Net income – basic	¥ 93.67	¥ 71.65	¥ 125.85	¥ 150.26
Net income – diluted	85.97	71.64	125.71	150.01
Equity	1,104.21	1,176.83	1,249.32	1,368.27
Cash dividends, applicable to period	20.00	40.00	50.00	60.00
<b>Cash flows:</b>				
Net cash provided by operating activities	¥ 15,808	¥ 23,196	¥ 6,619	¥ 20,879
Net cash (used in) provided by investing activities	(9,951)	5,246	(2,907)	(1,330)
Net cash used in financing activities	(6,507)	(12,122)	(12,712)	(5,900)
Interest coverage ratio (times)	34.5	70.6	36.1	218.7
Debt to cash flow ratio (%)	145.8	54.7	104.0	26.9
<b>At year-end:</b>				
Total current assets	¥ 83,431	¥ 91,231	¥ 82,735	¥ 93,893
Net property, plant and equipment	40,850	37,237	32,676	30,395
Total assets	147,148	150,238	139,980	150,458
Long-term debt	23,047	12,686	6,882	5,614
Equity	97,126	103,500	108,240	118,637
Return on equity (ROE) (%)	8.8	6.3	10.4	11.5
Return on total assets (ROA) (%)	5.7	4.3	7.6	9.0
Equity ratio (%)	66.0	68.9	77.3	78.9
Equity ratio on stock price basis (%)	68.7	101.8	142.3	163.0
Price earnings ratio (PER) (times)	12.3	24.3	18.3	18.8
Dividend on equity (DOE) (%)	1.9	3.5	4.1	4.6
Issued shares (thousands)	90,704	87,963	86,659	86,751
Number of employees	2,500	2,335	2,308	2,312

Notes: 1. U.S. dollar amounts have been translated from yen, solely for the convenience of the reader, at the rate of ¥94.05 to U.S.\$1.00, the exchange rate prevailing on March 31, 2013.

2. See Notes 2, 15) and 13 of Notes to Consolidated Financial Statements in respect of per share data.

3. Equity comprises shareholders' equity and accumulated other comprehensive income.

Millions of yen							Thousands of U.S. dollars	
2007	2008	2009	2010	2011	2012	2013		2013
¥ 100,486	¥ 103,394	¥ 101,619	¥ 110,594	¥ 110,812	¥ 114,416	¥ 119,066	\$ 1,265,987	
35,484	36,513	35,947	34,710	34,437	35,385	41,501	441,267	
44,590	46,510	50,178	46,244	45,636	52,299	52,884	562,293	
20,412	20,371	15,494	29,640	30,739	26,732	24,681	262,427	
91	97	65	53	36	23	7	74	
21,039	20,483	15,824	28,610	31,074	27,791	25,592	272,109	
7,891	7,832	5,701	9,887	9,741	10,630	9,071	96,448	
13,148	12,651	10,123	18,723	21,333	17,161	16,521	175,661	
3,556	3,151	2,953	1,315	1,651	3,281	3,609	38,368	
4,761	4,593	4,210	3,421	2,976	2,949	3,291	34,991	
13,663	12,942	18,458	14,123	13,221	17,225	16,720	177,777	
¥ 151.58	¥ 146.15	¥ 119.08	¥ 220.10	¥ 249.71	¥ 196.96	¥ 195.81	\$ 2.08	
151.31	145.94	118.97	219.85	249.42	196.76	195.51	2.08	
1,481.83	1,494.48	1,472.32	1,614.08	1,793.15	1,887.81	1,998.44	21.25	
65.00	80.00	80.00	80.00	90.00	100.00	100.00	1.06	
¥ 14,959	¥ 15,468	¥ 11,849	¥ 26,110	¥ 17,768	¥ 21,483	¥ 9,943	\$ 105,718	
(5,846)	(2,083)	(5,619)	(829)	(7,676)	(10,273)	(4,596)	(48,866)	
(5,691)	(11,415)	(11,373)	(6,753)	(1,570)	(8,559)	(21,557)	(229,211)	
164.3	163.6	165.5	558.1	488.5	1,285.0	3,037.8		
36.4	34.1	5.5	2.5	1.1	1.1	1.9		
¥ 100,820	¥ 102,754	¥ 101,053	¥ 118,832	¥ 137,668	¥ 140,288	¥ 132,583	\$ 1,409,704	
30,485	29,849	28,665	26,574	24,957	25,523	27,420	291,549	
159,099	156,547	151,012	166,878	184,801	198,801	199,641	2,122,707	
5,446	5,278	154	75	152	179	145	1,538	
128,587	126,998	125,181	137,343	156,099	164,514	164,808	1,752,346	
10.6	9.9	8.0	14.3	14.5	10.7	10.0		
8.5	8.0	6.6	11.8	12.1	8.9	8.3		
80.8	81.1	82.9	82.3	84.5	82.8	82.6		
165.3	126.2	154.3	143.1	156.2	155.0	183.8		
20.0	15.9	23.0	12.7	13.3	17.9	22.7		
4.6	5.4	5.4	5.2	5.3	5.4	5.1		
86,825	86,867	86,916	86,992	87,053	87,147	82,469		
2,409	2,483	2,690	2,756	2,867	3,053	3,050		

# Consolidated Balance Sheets

Santen Pharmaceutical Co., Ltd. and Subsidiaries  
As of March 31, 2013 and 2012

	Millions of yen		Thousands of U.S. dollars (Note 3)
	2013	2012	2013
<b>ASSETS</b>			
<b>Current assets:</b>			
Cash and cash equivalents (Note 6)	¥ 59,797	¥ 75,035	\$ 635,802
Short-term investments (Notes 6 and 7)	2,094	3,939	22,265
Trade receivables (Note 6):			
Notes	763	625	8,111
Accounts	43,078	37,299	458,033
Allowance for doubtful receivables	(2)	(1)	(20)
Net trade receivables	43,839	37,923	466,124
Inventories (Note 8)	20,949	17,949	222,744
Deferred tax assets (Note 16)	1,880	1,921	19,995
Other current assets	4,024	3,521	42,774
Total current assets	132,583	140,288	1,409,704
 <b>Property, plant and equipment (Notes 9 and 10):</b>			
Land	8,241	8,213	87,621
Buildings and structures	42,807	41,058	455,154
Machinery and equipment	11,818	11,258	125,662
Tools, furniture and vehicles	11,936	11,320	126,909
Lease assets	252	242	2,676
Construction in progress	2,455	1,366	26,098
Total	77,509	73,457	824,120
Accumulated depreciation and impairment loss	(50,089)	(47,934)	(532,571)
Net property, plant and equipment	27,420	25,523	291,549
 <b>Investments and other assets:</b>			
Investments in affiliates (Note 6)	16	16	166
Investment securities (Notes 6 and 7)	18,158	12,396	193,070
Goodwill	5,936	5,802	63,118
In-process research and development	6,768	5,942	71,961
Other intangible assets	1,420	1,134	15,096
Deferred tax assets (Note 16)	4,460	6,500	47,425
Other assets	2,880	1,200	30,618
Total investments and other assets	39,638	32,990	421,454
 Total assets	¥199,641	¥198,801	\$2,122,707

See accompanying notes to consolidated financial statements.

	Millions of yen		Thousands of U.S. dollars (Note 3)
	2013	2012	2013
<b>LIABILITIES AND NET ASSETS</b>			
<b>Current liabilities:</b>			
Trade accounts payable (Note 6)	¥ 9,266	¥ 8,075	\$ 98,525
Other payables (Note 6)	9,868	9,009	104,927
Accrued expenses	4,202	4,486	44,678
Income taxes payable (Notes 6 and 16)	3,039	5,283	32,309
Other current liabilities	636	573	6,761
Total current liabilities	27,011	27,426	287,200
<b>Non-current liabilities:</b>			
Long-term debt (Note 11)	145	179	1,538
Retirement and severance benefits (Note 12)	3,664	3,459	38,963
Retirement and severance benefits for directors (Note 12)	249	223	2,647
Deferred tax liabilities (Note 16)	2,269	1,996	24,128
Asset retirement obligation	160	162	1,706
Other liabilities	1,011	495	10,727
Total non-current liabilities	7,498	6,514	79,709
<b>Contingent liabilities (Note 17)</b>			
Total liabilities	34,509	33,940	366,909
<b>Net assets (Note 13):</b>			
Shareholders' equity:			
Common stock (Note 13):			
Authorized – 220,000,000 shares (220,000,000 shares in 2012)			
Issued – 82,469,103 shares (87,146,803 shares in 2012)	7,081	6,695	75,289
Capital surplus (Note 13)	7,775	8,049	82,672
Retained earnings	151,002	156,030	1,605,550
Treasury stock, at cost:			
900 shares (1,246 shares in 2012)	(2)	(4)	(27)
Total shareholders' equity	165,856	170,770	1,763,484
Accumulated other comprehensive income (loss):			
Unrealized gains on securities, net of taxes (Note 7)	1,920	51	20,416
Foreign currency translation adjustments	(2,968)	(6,307)	(31,554)
Total accumulated other comprehensive income (loss)	(1,048)	(6,256)	(11,138)
Stock subscription rights (Note 14)	324	347	3,452
Total net assets	165,132	164,861	1,755,798
<b>Total liabilities and net assets</b>	<b>¥199,641</b>	<b>¥198,801</b>	<b>\$2,122,707</b>

# Consolidated Statements of Income and Comprehensive Income

Santen Pharmaceutical Co., Ltd. and Subsidiaries  
For the years ended March 31, 2013, 2012 and 2011

	Millions of yen			Thousands of U.S. dollars (Note 3)
	2013	2012	2011	2013
Net sales	<b>¥119,066</b>	¥114,416	¥110,812	<b>\$1,265,987</b>
Cost of sales	<b>41,501</b>	35,385	34,437	<b>441,267</b>
Gross profit	<b>77,565</b>	79,031	76,375	<b>824,720</b>
Selling, general and administrative expenses	<b>52,884</b>	52,299	45,636	<b>562,293</b>
Operating income	<b>24,681</b>	26,732	30,739	<b>262,427</b>
Other income (expenses):				
Interest and dividend income	<b>522</b>	529	521	<b>5,550</b>
Dividend income of insurance	<b>158</b>	143	137	<b>1,680</b>
Exchange gains (losses), net	<b>92</b>	107	(123)	<b>977</b>
Interest expense	<b>(7)</b>	(23)	(36)	<b>(74)</b>
Gain on sale of investment securities	—	57	—	—
Loss on sale of investment securities	—	(15)	—	—
Write-down of investment securities (Note 7)	—	—	(150)	—
Office transfer expenses of U.S. subsidiaries	—	—	(135)	—
Loss on adjustment for change of accounting standard for asset retirement obligations	—	—	(109)	—
Loss on impairment of fixed assets (Note 10)	—	(19)	—	—
Other, net	<b>146</b>	280	230	<b>1,549</b>
Income before income taxes	<b>25,592</b>	27,791	31,074	<b>272,109</b>
Income taxes (Note 16):				
Current	<b>7,908</b>	9,912	9,970	<b>84,086</b>
Deferred	<b>1,163</b>	718	(229)	<b>12,362</b>
	<b>9,071</b>	10,630	9,741	<b>96,448</b>
Income before minority interests	<b>16,521</b>	17,161	21,333	<b>175,661</b>
Net income	<b>16,521</b>	17,161	21,333	<b>175,661</b>
Income before minority interests	<b>16,521</b>	17,161	21,333	<b>175,661</b>
Other comprehensive income (loss) (Note 4):				
Unrealized gains (losses) on securities, net of taxes	<b>1,869</b>	494	(579)	<b>19,869</b>
Foreign currency translation adjustments	<b>3,339</b>	(689)	(957)	<b>35,506</b>
Other comprehensive income (loss)	<b>5,208</b>	(195)	(1,536)	<b>55,375</b>
Total comprehensive income	<b>21,729</b>	16,966	19,797	<b>231,036</b>
Total comprehensive income attributable to:				
Owners of the parent	<b>¥ 21,729</b>	¥ 16,966	¥ 19,797	<b>\$ 231,036</b>
Minority interests	—	—	—	—
Per share data:		Yen		U.S. dollars (Note 3)
	2013	2012	2011	2013
Net income – basic	<b>¥ 195.81</b>	¥ 196.96	¥ 249.71	<b>\$ 2.08</b>
Net income – diluted	<b>195.51</b>	196.76	249.42	<b>2.08</b>
Cash dividends, applicable to the period	<b>100.00</b>	100.00	90.00	<b>1.06</b>

See accompanying notes to consolidated financial statements.

# Consolidated Statements of Changes in Net Assets

Santen Pharmaceutical Co., Ltd. and Subsidiaries  
For the years ended March 31, 2013, 2012 and 2011

	Millions of yen						
	Common stock	Capital surplus	Retained earnings	Treasury stock, at cost	Unrealized gains (losses) on securities, net of taxes	Foreign currency translation adjustments	Stock subscription rights
Balance at April 1, 2010	¥6,539	¥7,234	¥133,053	¥ (4,958)	¥ 136	¥(4,661)	¥260
Exercise of stock options	76	76					
Cash dividends			(6,808)				
Net income			21,333				
Repurchase of treasury stock, net				(26)			
Disposal of treasury stock		659			4,982		
Other, net					(579)	(957)	45
Balance at March 31, 2011	¥6,615	¥7,969	¥147,578	¥ (2)	¥ (443)	¥(5,618)	¥305
Exercise of stock options	80	80					
Cash dividends			(8,709)				
Net income			17,161				
Repurchase of treasury stock, net				(2)			
Disposal of treasury stock		0			0		
Other, net					494	(689)	42
Balance at March 31, 2012	¥6,695	¥8,049	¥156,030	¥ (4)	¥ 51	¥(6,307)	¥347
Exercise of stock options	386	386					
Cash dividends			(8,469)				
Net income			16,521				
Repurchase of treasury stock, net			(13,738)				
Retirement of treasury stock		(660)	(13,080)	13,740			
Other, net					1,869	3,339	(23)
<b>Balance at March 31, 2013</b>	<b>¥7,081</b>	<b>¥7,775</b>	<b>¥151,002</b>	<b>¥ (2)</b>	<b>¥1,920</b>	<b>¥(2,968)</b>	<b>¥324</b>

	Thousands of U.S. dollars (Note 3)						
	Common stock	Capital surplus	Retained earnings	Treasury stock, at cost	Unrealized gains (losses) on securities, net of taxes	Foreign currency translation adjustments	Stock subscription rights
Balance at April 1, 2012	\$71,185	\$85,583	\$1,659,015	\$ (46)	\$ 547	\$(67,060)	\$3,690
Exercise of stock options	4,104	4,104					
Cash dividends			(90,045)				
Net income			175,661				
Repurchase of treasury stock, net			(146,076)				
Retirement of treasury stock		(7,015)	(139,081)	146,095			
Other, net					19,869	35,506	(238)
<b>Balance at March 31, 2013</b>	<b>\$75,289</b>	<b>\$82,672</b>	<b>\$1,605,550</b>	<b>\$ (27)</b>	<b>\$20,416</b>	<b>\$(31,554)</b>	<b>\$3,452</b>

See accompanying notes to consolidated financial statements.

# Consolidated Statements of Cash Flows

Santen Pharmaceutical Co., Ltd. and Subsidiaries  
For the years ended March 31, 2013, 2012 and 2011

	Millions of yen			Thousands of U.S. dollars (Note 3)
	2013	2012	2011	2013
<b>Cash flows from operating activities:</b>				
Income before income taxes	¥ 25,592	¥ 27,791	¥ 31,074	\$ 272,109
Depreciation and amortization	2,657	2,787	2,976	28,247
Amortization of goodwill	634	162	—	6,744
Loss on impairment of fixed assets (Note 10)	—	19	—	—
Increase in retirement and severance benefits	187	179	359	1,987
Interest and dividend income	(522)	(529)	(521)	(5,550)
Interest expense	7	23	36	74
(Increase) decrease in trade receivables	(5,560)	1,037	(3,893)	(59,112)
Increase in inventories	(2,589)	(3,294)	(1,299)	(27,527)
Increase in trade accounts payable	1,170	2,034	522	12,443
Other, net	(1,790)	10	(11)	(19,040)
Subtotal	19,786	30,219	29,243	210,375
Interest and dividend income received	532	549	513	5,661
Interest expense paid	(3)	(17)	(36)	(35)
Income taxes paid	(10,372)	(9,268)	(11,952)	(110,283)
Net cash provided by operating activities	9,943	21,483	17,768	105,718
<b>Cash flows from investing activities:</b>				
Capital expenditures	(3,609)	(3,281)	(1,651)	(38,368)
Proceeds from sale of property, plant and equipment	37	6	188	394
Purchase of investment securities	(4,883)	(2,420)	(4,296)	(51,918)
Proceeds from sale of investment securities	1	377	20	12
Purchase of short-term investments	(807)	(1,783)	(5,873)	(8,577)
Proceeds from sale of short-term investments	4,680	7,632	3,922	49,748
Acquisition of subsidiary, net of cash acquired	—	(10,804)	—	—
Increase in loans receivable	—	(7)	(1)	—
Proceeds from collection of loans receivable	3	8	—	29
Other, net	(18)	(1)	15	(186)
Net cash used in investing activities	(4,596)	(10,273)	(7,676)	(48,866)
<b>Cash flows from financing activities:</b>				
Proceeds from short-term borrowings	—	—	259	—
Repayment of short-term borrowings	—	—	(776)	—
Repurchase of treasury stock	(13,763)	(2)	(26)	(146,349)
Disposal of treasury stock	—	0	5,641	—
Dividends paid	(8,469)	(8,706)	(6,808)	(90,044)
Other, net	675	149	140	7,182
Net cash used in financing activities	(21,557)	(8,559)	(1,570)	(229,211)
<b>Effect of exchange rate changes on cash and cash equivalents</b>	972	(98)	(389)	10,336
<b>Net (decrease) increase in cash and cash equivalents</b>	(15,238)	2,553	8,133	(162,023)
<b>Cash and cash equivalents at beginning of year</b>	75,035	72,482	64,349	797,825
<b>Cash and cash equivalents at end of year</b>	¥ 59,797	¥ 75,035	¥ 72,482	\$ 635,802

See accompanying notes to consolidated financial statements.

	Millions of yen			Thousands of U.S. dollars (Note 3)
	2013	2012	2011	2013
<b>Additional cash flow information:</b>				
Assets and liabilities increased by acquisition of shares of subsidiary:				
Current assets	¥—	¥ 1,171	¥—	\$—
Non-current assets	—	6,251	—	—
Goodwill	—	6,195	—	—
Current liabilities	—	(340)	—	—
Non-current liabilities	—	(2,320)	—	—
Foreign currency translation adjustments	—	(2)	—	—
Acquisition price	—	10,955	—	—
Other payables	—	(32)	—	—
Cash and cash equivalents	—	(119)	—	—
Payments for purchases of shares of subsidiary	¥—	¥10,804	¥—	\$—

# Notes to Consolidated Financial Statements

Santen Pharmaceutical Co., Ltd. and Subsidiaries

## 1. Basis of Presentation of Consolidated Financial Statements

The consolidated financial statements of Santen Pharmaceutical Co., Ltd. (the "Company") have been prepared in accordance with the provisions set forth in the Japanese Financial Instruments and Exchange Act and its related accounting regulations, and in conformity with accounting principles generally accepted in Japan ("Japanese GAAP"), which are different in certain respects as to application and disclosure requirements from International Financial Reporting Standards.

The accounts of consolidated overseas subsidiaries have been prepared in accordance with either International Financial Reporting Standards or U.S. generally accepted accounting principles, as required under "Practical Solution on Unification of Accounting Policies Applied to Foreign Subsidiaries for Consolidated Financial Statements" (Practical Issues Task Force No. 18) issued and revised by the Accounting Standards Board of Japan ("ASBJ"). In this case, adjustments for the following five items are required in the consolidation process so that their impact on net income is accounted for in accordance with Japanese GAAP unless the impact is not material.

- (a) Goodwill not subject to amortization
- (b) Actuarial gains and losses of defined-benefit retirement plans recognized outside profit and loss
- (c) Capitalized expenditures for research and development activities
- (d) Fair value measurement of investment properties and revaluation of property, plant and equipment and intangible assets
- (e) Accounting for net income attributable to minority interests

The consolidated financial statements have been restructured and translated into English (with certain expanded disclosures) from the consolidated financial statements of the Company prepared in accordance with Japanese GAAP and filed with the appropriate Local Finance Bureau of the Ministry of Finance as required by the Financial Instruments and Exchange Act. Certain supplementary information included in the statutory Japanese language consolidated financial statements is not presented in these consolidated financial statements.

## 2. Summary of Significant Accounting Policies

### 1) Principles of consolidation

The consolidated financial statements include the accounts of the Company and its subsidiaries (the "Companies"). All significant intercompany balances and transactions are eliminated on consolidation.

During the year ended March 31, 2012, the Company established two new subsidiaries (Santen India Private Limited, Santen Holdings EU B.V.) and acquired one subsidiary (Novagali Pharma S.A.S. ("Novagali")).

Investment in an affiliated company is stated at cost due to immateriality.

Note: In April, 2013, Novagali changed its name to Santen S.A.S.

classified into three categories; trading, held-to-maturity, or other securities.

Based on this classification, all trading securities and any held-to-maturity and other securities with a maturity of less than one year are included in current assets. All other securities are included in investment securities as noncurrent assets.

Those classified as other securities with an available market value are reported at fair value with unrealized holding gains (losses), net of related taxes, reported as a separate component of accumulated other comprehensive income.

Realized gains and losses on sales of such securities are determined by the moving average cost method. Other securities with no available market value are carried at cost, which is determined by the moving average cost method.

In addition, this standard also requires the recognition of an impairment loss on golf membership rights, included in other assets, on the consolidated balance sheets, when the market value declines substantially and the decline is not expected to recover.

### 2) Use of estimates

The preparation of the consolidated financial statements in conformity with Japanese GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities. Actual results could differ from those estimates.

### 3) Short-term investments, investment securities and golf membership rights (see Notes 6 and 7)

The Company and its domestic subsidiary have adopted the "Accounting Standard for Financial Instruments" which was issued and revised by the Business Accounting Council in Japan. In accordance with this standard, securities are

### 4) Derivative instruments (see Note 6)

Derivatives are initially measured at fair value and are subsequently remeasured to fair value at each reporting date. Apart from those derivatives designated as qualifying hedging instruments, all changes in carrying value are recognized in profit. The Company utilizes derivatives for hedging the risk arising from fluctuation in foreign currency exchange rates and

interest rates and does not enter into derivatives for trading or speculative purposes. Derivatives that are designated as qualifying hedging instruments are accounted for using deferred hedge accounting. Recognition of gains or losses resulting from changes in fair values of derivative financial instruments are deferred until the related losses or gains on the hedged items are realized if the derivative financial instruments are used as hedges and meet certain hedging criteria. Foreign exchange contracts that meet the criteria are accounted for under the allocation method. The allocation method requires recognized foreign currency receivables or payables to be translated using the corresponding foreign exchange contract rates. Interest rate swaps that meet the criteria are accounted for under the special method, as regulated in the accounting standard, as if the interest rates under interest rate swaps were originally applied to underlying borrowings.

The Company has also developed a hedging policy to control various aspects of derivative instruments including authorization levels and transaction volumes. Based on this policy, the Company hedges the risk arising from fluctuations in foreign currency exchange rates, interest rates, and prices of securities. The Company evaluates hedge effectiveness by comparing the cumulative changes in cash flows from hedged items and corresponding changes in hedging derivative instruments. With respect to interest rate swaps under the special method, the evaluation of hedge effectiveness is omitted.

#### **5) Allowance for doubtful receivables**

Allowance for doubtful receivables is provided principally at an amount determined based on the historical experience of bad debts and the estimated uncollectible amounts based on the specific analysis of receivables with default possibility.

#### **6) Inventories (see Note 8)**

Inventories of the Company and its domestic subsidiary are stated at the lower of average cost or net realizable value under the "Accounting Standard for Measurement of Inventories" which was issued by ASBJ.

Inventories of consolidated foreign subsidiaries are principally stated at the lower of first-in, first-out cost or net realizable value.

#### **7) Property, plant and equipment (excluding lease assets)**

Property, plant and equipment is stated at cost. For the Company and its domestic subsidiary, depreciation of buildings acquired prior to April 1, 1998, and other property, plant and equipment is computed over the estimated useful lives of the assets using the declining-balance method. Buildings (other than leasehold improvements) which were acquired on or after April 1, 1998, are depreciated using the straight-line method for the Company and its domestic

subsidiary. For all overseas subsidiaries, depreciation is computed over the estimated useful lives of the assets using the straight-line method.

The principal estimated useful lives are as follows:

Buildings and structures	31 to 50 years
Machinery and equipment	7 to 8 years
Tools, furniture and vehicles	4 to 10 years

#### **8) In-process research and development and Other intangible assets (excluding lease assets)**

In-process research and development resources acquired through a business combination are capitalized as intangible assets at the fair value allocated in the acquisition accounting. In-process research and development and other intangible assets are amortized over their useful lives on a straight-line-method from the point when they are available for use.

#### **9) Leases (see Note 9)**

Finance leases, except for certain immaterial leases, are capitalized and depreciated over the leased property's estimated useful lives or lease terms, in accordance with the "Accounting Standard for Lease Transactions" and the "Guidance on Accounting Standard for Lease Transactions" which were issued by ASBJ. As permitted under the accounting standard, the Company and its domestic subsidiary account for finance leases commencing prior to April 1, 2008 which do not transfer ownership of the leased property to the lessee as operating leases with disclosure of certain "as if capitalized" information.

#### **10) Goodwill**

Goodwill recognized through the acquisition of Novagali is amortized using the straight-line method over the period of expected benefit (10 years).

#### **11) Impairment of fixed assets (see Note 10)**

In accordance with the "Accounting Standards for Impairment of Fixed Assets" which was issued by the Business Accounting Council in Japan, fixed assets, such as property, plant and equipment and intangible assets are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable.

Recoverability of assets to be held and used is measured by comparing the carrying amount of an asset, or group of assets, to the estimated undiscounted future cash flows expected to be generated. If the carrying amount of an asset, or group of assets, exceeds its estimated future cash flows, an impairment charge is recognized for the amount by which the carrying amount of the asset exceeds the greater of its net realizable value or value in use.

## **12) Retirement and severance benefits (see Note 12)**

Employees of the Company and certain subsidiaries are generally entitled to lump-sum severance and, in certain cases, annuity payments on retirement, based on current rates of pay, length of service and certain other factors.

The Companies have adopted the "Accounting Standard for Retirement Benefits" which was issued by the Business Accounting Council. In accordance with this standard, the allowance for retirement benefits for employees is provided based on the estimated retirement benefit obligation and the plan assets. Actuarial gains and losses are amortized from the year in which the actuarial gains and losses are incurred, using the straight-line method over the estimated average remaining service years of employees.

The Company has a retirement benefit scheme, which is a combination of lump-sum severance plan, cash balance and defined contribution pension plan. The Company also has a retirement benefits trust.

Certain overseas subsidiaries have a retirement benefit scheme which is a combination of a cash balance and defined contribution pension plan, and other overseas subsidiaries have defined contribution pension plans. The amounts contributed under the plans are charged to income.

In addition, the Company has an unfunded retirement benefit plan for directors. The amounts required under the plan have been fully accrued according to internal regulations.

## **13) Foreign currency translation**

All monetary assets and liabilities denominated in foreign currencies are translated at the rate of exchange prevailing on the balance sheet date, except for those items covered by forward exchange contracts.

The Company and its domestic subsidiary have adopted the "Accounting Standard for Foreign Currency Transactions" which was issued by the Business Accounting Council in Japan.

Financial statements of overseas subsidiaries are translated into yen at year-end rates for all assets and liabilities and at weighted average rates for income and expense accounts. Adjustments resulting from the translation of financial statements are reflected under the caption, "Foreign currency translation adjustments," in net assets.

## **14) Research and development (see Note 15)**

Research and development expenditures are charged to income when incurred.

## **15) Net income and dividends per share (see Note 13)**

The computation of basic net income per share is based on the weighted average number of shares of common stock outstanding during each period. The average number of shares used in the computation for the years ended March

31, 2013, 2012 and 2011 was 84,368 thousand, 87,127 thousand and 85,433 thousand, respectively.

The diluted net income per share assumes the dilution that could occur if securities or other contracts to issue common stock were exercised or converted into common stock or resulted in the issuance of common stock. The average number of shares used in the computation for the years ended March 31, 2013, 2012 and 2011 was 84,500 thousand, 87,214 thousand and 85,534 thousand, respectively.

Cash dividends per share shown in the accompanying Consolidated Statements of Income and Comprehensive Income are the amounts applicable to the respective years.

## **16) Income taxes (see Note 16)**

Income taxes are accounted for by the asset and liability method. Deferred tax assets and liabilities are recognized for the estimated future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases, operating loss carryforwards and foreign tax credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities resulting from a change in tax rates is recognized in income in the period that includes the enactment date.

## **17) Cash and cash equivalents**

Cash and cash equivalents mainly include cash on hand, readily available deposits and all highly liquid debt investments, generally with a maturity of three months or less, that are readily convertible to known amounts of cash and are so near maturity that they present insignificant risk of changes in value.

## **18) Reclassifications**

Certain reclassifications have been made to prior years' consolidated financial statements to conform with the presentation used for the year ended March 31, 2013.

## **19) Changes in accounting policies**

Effective March 31, 2011, the Company adopted the "Accounting Standard for Presentation of Comprehensive Income" (ASBJ Statement No. 25 issued on June 30, 2010) and the "Revised Accounting Standard for Consolidated Financial Statements" (ASBJ Statement No. 22 revised on June 30, 2010).

Effective April 1, 2011, the Company and its domestic subsidiary adopted the "Accounting Standard for Accounting Changes and Error Corrections" (ASBJ Statement No. 24 issued on December 4, 2009) and the "Guidance on Accounting Standard for Accounting Changes and Error Corrections" (ASBJ Guidance No. 24 issued on December 4, 2009).

Effective April 1, 2012, the Company and its domestic subsidiary adopted the new depreciation method to comply with Corporate Tax Law revised in 2012 for property, plant and equipment acquired after April 1, 2012. The effect of this adoption was to increase operating income and income before income taxes by ¥45 million (\$484 thousand).

## 20) Unapplied accounting standards

"Accounting Standard for Retirement Benefits" (ASBJ Statement No. 26, May 17, 2012) and "Guidance on Accounting Standard for Retirement Benefits" (ASBJ Guidance No. 25, May 17, 2012)

### (1) Summary

Under the amended rule, actuarial gains and losses and past service costs that are yet to be recognized in profit or loss would be recognized within the net asset section, after adjusting for tax effects, and the deficit or surplus would be recognized as a liability or asset without any adjustments.

For determining method of attributing expected benefit to periods, the Standard now allows to choose benefit formula basis, as well as straight-line basis. Method for determination of discount rate has also been amended.

### (2) Effective dates

Effective for the beginning of annual periods ending on or

after March 31, 2014.

### (3) Effect of application of the standard

Retirement and severance benefits are now calculated as net defined benefit liabilities which are the amount of retirement benefit obligations deducting plan assets, and the unrecognized actuarial gains and losses will be included in the liability from the beginning of annual period ending on March 31, 2014. Furthermore, the Company reviewed the method used to calculate for retirement benefit obligations and service cost, and changed to the method of attributing expected benefits to periods from straight-line basis to benefit formula basis. Along with this, the Company changed the method used to determine discount rates based on the average remaining service period for employees to a method that uses a single weighted average discount rate reflecting the expected payment period as well as the amount for each payment period.

As a result of this application, accumulated other comprehensive income decreased by ¥1,713 million (\$18,223 thousand) and retained earnings increased by ¥227 million (\$2,423 thousand) at the beginning of annual period ending on March 31, 2014. There are no material effects on operating income and income before income taxes for the annual period ending on March 31, 2014.

## 3. Translation into United States Dollars

The accompanying consolidated financial statements are expressed in Japanese yen and, solely for the convenience of the reader, have been translated into United States dollars at the rate of ¥94.05 to U.S.\$1.00, the exchange rate

prevailing on March 31, 2013. The translation should not be construed as a representation that the Japanese yen have been, could have been, or could in the future be converted into United States dollars at that rate or any other rate.

## 4. Other Comprehensive Income (Loss)

Amounts reclassified to net income in the current period that were recognized in other comprehensive income (loss) in the current or previous periods and the tax effects for each component of other comprehensive income (loss) for the years ended March 31, 2013 and 2012 were as follows:

	Millions of yen		Thousands of U.S. dollars
	2013	2012	
<b>Unrealized gains on securities:</b>			
Increase during the year	¥ 2,896	¥ 881	\$ 30,795
Reclassification adjustments	—	(57)	—
Sub-total, before tax	2,896	824	30,795
Tax expense	(1,027)	(330)	(10,926)
Sub-total, net of tax	1,869	494	19,869
<b>Foreign currency translation adjustments:</b>			
Increase (decrease) during the year	3,339	(689)	35,506
Total other comprehensive income (loss)	¥ 5,208	¥(195)	\$ 55,375

## 5. Business Combination

### 1) Overview of the business combination

#### i. Name and business of the acquired company

Name of the acquired company: Novagali Pharma S.A.  
Business of the acquired company:

Development and commercializing of ophthalmic products

#### ii. Main reasons for the business combination

Novagali is a pharmaceutical company that develops ophthalmic products in the dry eye domain and it also commercializes OTC pharmaceuticals. The Company believes that Novagali will play an important role with its outstanding R&D capability as well as its unique pharmaceutical technologies.

Especially, Novasorb technology will enhance the Companies' drug formulation ability as a whole. Based on Novasorb technology, Cyclokat (generic name: ciclosporin) is currently undergoing development. This is a development product in late stage pipeline in the dry eye domain. When Cyclokat is approved for production and marketing, it will be released as Europe's first prescription pharmaceutical for the treatment of dry eye and it will be also able to strengthen the Companies' global business.

#### iii. Date of the business combination

October 11, 2011

#### iv. Legal format of the business combination

Acquisition of the shares for cash consideration

#### v. Name of the company after business combination

Novagali Pharma S.A.\*

#### vi. Shareholding status after business combination

Wholly owned subsidiary of the Company

#### vii. Main basis behind the determination of the acquiring company

Acquired 100% of the shares of Novagali for cash consideration

### 2) Operating result of the acquired company for the year ended March 31, 2012

Operating results of the acquired company from October 11, 2011 to December 31, 2011 were included in the consolidated results of the Company for the year ended March 31, 2012.

### 3) Acquisition cost of the acquired company

Cash payment for acquisition

¥10,402 million (\$126,559 thousand)

Other direct costs for the acquisition

¥553 million (\$6,727 thousand)

Total acquisition cost

¥10,955 million (\$133,286 thousand)

### 4) Goodwill recognized and method and period of amortization

#### i. Goodwill recognized at the date of the business combination

¥6,195 million (\$75,376 thousand)

#### ii. Method and period of amortization

The excess of cost over the fair value of the underlying net assets at fair value at the date of the acquisition was recognized as goodwill. The goodwill is being amortized using the straight-line method over 10 years.

### 5) Breakdown of acquired assets and liabilities as of date of business combination

Current assets	¥1,171 million	(\$14,247 thousand)
Fixed assets	¥12,446 million	(\$151,432 thousand)
Total assets	¥13,617 million	(\$165,679 thousand)

Current liabilities	¥340 million	(\$4,134 thousand)
Fixed liabilities	¥2,320 million	(\$28,227 thousand)
Total liabilities	¥2,660 million	(\$32,361 thousand)

### 6) Significant intangible assets other than goodwill acquired in the business combination included in the acquisition cost

In-process research and development

¥6,170 million (\$75,065 thousand)

This intangible asset is amortized over the estimated useful life.

### 7) Estimated impact on the consolidated statements of income and comprehensive income for the year ended March 31, 2012 if the business combination had been completed as of the beginning of the year ended March 31, 2012

Since estimated impact is minimal, it is omitted.

\* In March, 2012, Novagali changed its company form, and it became Novagali Pharma S.A.S. under the French regulation.

## 6. Financial Instruments

The Companies have adopted the “Accounting Standard for Financial Instruments” and the “Guideline on Disclosures about Fair Value of Financial Instruments.”

Information on Financial instruments for the year ended March 31, 2013, 2012 and 2011 is as follows:

### 1) Policies for financing activities

The Companies principally use highly liquid and safe financial instruments in financing activities. The Companies basically rely on their own resources to finance operations and use derivative financial instruments only to hedge foreign exchange rate risk for foreign currency denominated assets and liabilities and do not use derivative financial instrument for speculative purposes.

### 2) Risk management

Trade receivables are exposed to customer credit risk. To manage this risk, the Company performs due date and credit limit controls in accordance with the Companies' credit management rules and periodically assesses the financial reliability of each customer taking into account the customer's financial position and other factors.

Bonds in short-term investments are exposed to the credit risk of the issuing institution. The Company invests only in high-rated bonds.

Investment securities are exposed to market risk, most of which are stocks of companies with which the Company has business relationships. The Company periodically reviews the fair market values of these securities and reports on them at the Company's board meeting.

Trade accounts payable, other payables and income taxes payable (the “operating payables”) are due within one year.

Bank loans in short-term borrowings and long-term debt do not occur regularly. The Companies use them as short-term funding for business necessities according to the situation.

Operating payables and the bank loans are exposed to liquidity risk. The Company manages the risk by monitoring the monthly cash flows of each group company.

To reduce credit risk, the Company uses derivative instruments according to its policies for hedging, including rules for authorization levels, transaction volumes and entering into transactions only with highly rated banks.

The book value and fair value of the financial instruments on the consolidated balance sheet at March 31, 2013 and 2012 were as follows:

	Millions of yen					
	2013			2012		
	Book value	Fair value	Difference	Book value	Fair value	Difference
Cash and cash equivalents	¥59,797	¥59,797	¥(0)	¥75,035	¥75,035	¥(0)
Trade receivables	43,841	43,841	—	37,924	37,924	—
Short-term investments and Investment securities:						
Time deposits	86	86	—	198	198	—
Held-to-maturity	4,218	4,218	(0)	4,239	4,236	(3)
Other securities	15,477	15,477	—	11,754	11,754	—
Trade accounts payable	(9,266)	(9,266)	—	(8,075)	(8,075)	—
Other payables	(9,868)	(9,868)	—	(9,009)	(9,009)	—
Income taxes payable	(3,039)	(3,039)	—	(5,283)	(5,283)	—
Derivatives	—	—	—	—	—	—

## Notes to Consolidated Financial Statements

	Thousands of U.S. dollars		
	2013		
	Book value	Fair value	Difference
Cash and cash equivalents	\$635,802	\$635,798	\$ (4)
Trade receivables	466,144	466,144	—
Short-term investments and Investment securities:			
Time deposits	919	919	—
Held-to-maturity	44,851	44,846	(5)
Other securities	164,563	164,563	—
Trade accounts payable	(98,525)	(98,525)	—
Other payables	(104,927)	(104,927)	—
Income taxes payable	(32,309)	(32,309)	—
Derivatives	—	—	—

Notes: 1. Instruments with no fair market value are excluded in the table above.

2. Figures in parentheses indicate a liability or a decrease.

3. The following methods and assumptions were used to estimate fair value:

Cash and Trade receivables

– As these assets are settled in a short period of time, the fair value approximates book value.

Cash equivalents

– The fair values of held-to-maturity debt securities included in Cash and cash equivalents are based on the quoted market prices or the prices provided by corresponding financial institutions.

Short-term investments and Investment securities

– The fair values of listed stocks are based on year-end quoted stock market prices and those of bonds are based on the quoted market prices or the prices provided by corresponding financial institutions.

– The fair value of time deposits approximates the book value.

Short-term borrowings, Trade accounts payable, Other payables and Income taxes payable

– As these liabilities are settled in a short period, fair value approximates book value.

Derivatives

– There were no outstanding transactions at March 31, 2013 and 2012.

4. Financial Instruments with no fair market value as of March 31, 2013 and 2012 were as follows:

	Thousands of U.S. dollars		
	Millions of yen	2013	2012
Other securities:			
Unlisted securities	¥468	¥138	\$4,969
Investment limited partnerships	19	21	199
	¥487	¥159	\$5,168

These instruments are excluded from investment securities in the table above since there are no fair market values available for these instruments.

5. The maturity profile of the anticipated future contractual cash flows in relation to the Companies' financial assets at March 31, 2013 and 2012 were as follows:

	Millions of yen			Thousands of U.S. dollars	
	2013	2012		2013	2012
	Due within one year	Due after one year	Due within one year	Due within one year	Due after one year
Cash and cash equivalents	¥ 59,797	¥ —	¥ 75,035	¥ —	\$ 635,802
Trade receivables	43,841	—	37,924	—	466,144
Short-term investments and investment securities:					
Time deposits	86	—	198	—	919
Held-to-maturity	2,000	2,200	3,721	500	21,265
Other securities	—	—	—	—	—
	¥105,724	¥2,200	¥116,878	¥500	\$1,124,130
					\$23,392

6. See Note 11 of Notes to Consolidated Financial Statements in respect to maturities of long-term debt at March 31, 2013 and 2012.

## 7. Short-term Investments and Investment Securities

The following was a summary of held-to-maturity at market value at March 31, 2013 and 2012:

	Millions of yen					
	2013			2012		
	Book value	Fair value	Difference	Book value	Fair value	Difference
Securities with fair values exceeding book values:						
Corporate bonds	¥1,704	¥1,705	¥ 1	¥ —	¥ —	¥ —
Securities with fair values not exceeding book values:						
Corporate bonds	2,514	2,513	(1)	4,239	4,236	(3)
	¥4,218	¥4,218	¥(0)	¥4,239	¥4,236	¥(3)

	Thousands of U.S. dollars		
	2013		
	Book value	Fair value	Difference
Securities with fair values exceeding book values:			
Corporate bonds	\$18,119	\$18,125	\$ 6
Securities with fair values not exceeding book values:			
Corporate bonds	26,732	26,721	(11)
	\$44,851	\$44,846	\$ (5)

The following was a summary of other securities at market value at March 31, 2013 and 2012:

	Millions of yen					
	2013			2012		
	Acquisition cost	Book value	Difference	Acquisition cost	Book value	Difference
Securities with book values exceeding acquisition costs:						
Equity securities	¥12,012	¥15,061	¥3,049	¥ 4,043	¥ 5,195	¥ 1,152
Other	0	0	—	3	3	—
Securities with book values not exceeding acquisition costs:						
Equity securities	500	416	(84)	7,628	6,556	(1,072)
Other	—	—	—	—	—	—
	¥12,512	¥15,477	¥2,965	¥11,674	¥11,754	¥ 80

	Thousands of U.S. dollars		
	2013		
	Acquisition cost	Book value	Difference
Securities with book values exceeding acquisition costs:			
Equity securities	\$127,723	\$160,135	\$32,412
Other	0	0	—
Securities with book values not exceeding acquisition costs:			
Equity securities	5,317	4,428	(889)
Other	—	—	—
	\$133,040	\$164,563	\$31,523

The market prices in the table above do not include the unlisted securities. The book value of the unlisted securities at March 31, 2013 and 2012 were ¥471 million (\$5,002 thousand) and ¥143 million, respectively.

## Notes to Consolidated Financial Statements

Held-to-maturity debt securities sold during the year ended March 31, 2013 and 2012 were as follows:

	Millions of yen		Thousands of U.S. dollars
	2013	2012	2013
Cost of securities sold	¥—	¥809	\$—
Proceeds	—	794	—
Loss on sale	¥—	¥ (15)	\$—

Impairment loss on investment securities was ¥150 million for the year ended March 31, 2011.

If the year-end value of an investment security has declined by more than 50% of its acquisition cost, an impairment loss is recognized. When the year-end value has declined by less than 50% but more than 30%, an impairment loss is recognized if there is no possibility that the security will recover its value.

### 8. Inventories

Inventories at March 31, 2013 and 2012 consisted of the following:

	Millions of yen		Thousands of U.S. dollars
	2013	2012	2013
Merchandise and finished goods	¥16,703	¥14,672	\$177,602
Work in process	625	600	6,643
Raw materials and supplies	3,621	2,677	38,499
	¥20,949	¥17,949	\$222,744

### 9. Leases

Finance leases, commenced prior to April 1, 2008, which did not transfer ownership of the leased assets to the lessees, are accounted for as operating leases.

#### Finance leases

The equivalent purchase amount, accumulated depreciation and future minimum lease payments on an "as if capitalized" basis at March 31, 2013 and 2012 were as follows:

	Millions of yen		Thousands of U.S. dollars
	2013	2012	2013
<b>Tools, furniture and vehicles:</b>			
Equivalent purchase amount	¥—	¥—	\$—
Equivalent accumulated depreciation amount	—	—	—
Equivalent balance at year-end	—	—	—
<b>Future minimum lease payments:</b>			
Due within one year	¥—	¥—	\$—
Due after one year	—	—	—
	¥—	¥—	\$—

Lease payments, equivalent depreciation and equivalent interest expense for the three years ended March 31, 2013 were as follows:

	Millions of yen			Thousands of U.S. dollars
	2013	2012	2011	2013
Lease payments	¥—	¥13	¥143	\$—
Equivalent depreciation	¥—	¥12	¥133	\$—
Equivalent interest expense	¥—	¥ 0	¥ 1	\$—

#### Operating leases

Future minimum rents under non-cancellable operating leases at March 31, 2013 and 2012 consisted of the following:

	Millions of yen			Thousands of U.S. dollars
	2013	2012	2011	2013
Due within one year	¥ 428	¥201	¥4,546	\$—
Due after one year	847	491	9,006	\$—
	¥1,275	¥692	¥13,552	\$—

## 10. Impairment of Fixed Assets

The Company and its domestic subsidiary account for impairment of fixed assets in accordance with the "Accounting Standard for Impairment of Fixed Assets."

The Company and its domestic subsidiary review the recorded value of their property, plant and equipment and intangible assets to determine if the future cash flows from these properties will be sufficient to support the asset's recoverable amount.

Impairment loss recognized for the three years ended March 31, 2013 was as follows:

	Millions of yen			Thousands of U.S. dollars
	2013	2012	2011	2013
Land	¥—	¥—	¥—	\$—
Buildings and structures	—	19	—	—
Others	—	—	—	—
	¥—	¥19	¥—	\$—

For the year ended March 31, 2012, the Company recorded impairment loss related to building and structures

for its plant due to the decision to stop the use of a generator. The fair value was based on the disposal value.

## 11. Long-term Debt

Long-term debt at March 31, 2013 and 2012 consisted of the following:

Long-term borrowings are executed by Novagali.

	Millions of yen			Thousands of U.S. dollars
	2013	2012	2013	2013
Unsecured loan from governmental institution, due in installments by September 30, 2013, no interest	¥ —	¥ 14	\$ —	\$ —
Unsecured loan from governmental institution, due in installments by September 30, 2015, no interest	58	50	613	\$—
Lease obligations	87	115	925	\$—
	¥145	¥179	¥1,538	\$—

## Notes to Consolidated Financial Statements

The aggregate annual maturities of long-term debt at March 31, 2013 were as follows:

Years ending March 31	Millions of yen	Thousands of U.S. dollars
2015	¥ 74	\$ 784
2016	50	529
2017	5	53
2018	5	51
2019 and thereafter	11	121
	¥145	\$1,538

### 12. Retirement and Severance Benefits

As discussed in Note 2. 12), the Company has a retirement benefit scheme, which is a combination of lump-sum severance plan, cash balance and defined contribution pension plan. The Company also has a retirement benefit trust. Certain overseas subsidiaries also have a retirement benefit scheme, which is a combination of cash balance

and defined contribution pension plan and other overseas subsidiaries have defined contribution pension plans. The Company has an unfunded retirement benefit plan for directors. The amounts required under the plan have been fully accrued based on internal regulations.

The following table sets forth the details of the benefit obligation, plan assets and funded status of the Companies at March 31, 2013 and 2012.

	Millions of yen		Thousands of U.S. dollars
	2013	2012	
<b>For employees:</b>			
Benefit obligation at end of year	¥(17,372)	¥(14,926)	<b>\$(184,708)</b>
Fair value of plan assets at end of year	11,053	10,286	<b>117,517</b>
Funded status (benefit obligation in excess of plan assets)	(6,319)	(4,640)	<b>(67,191)</b>
Unrecognized actuarial loss	2,655	1,181	<b>28,228</b>
<b>For directors:</b>			
Accrued retirement benefit	(249)	(223)	<b>(2,647)</b>
Retirement and severance benefits recognized in the consolidated balance sheets	¥ (3,913)	¥ (3,682)	<b>\$(41,610)</b>

Retirement and severance costs of the Companies included the following components for the three years ended March 31, 2013.

	Millions of yen			Thousands of U.S. dollars
	2013	2012	2011	
<b>For employees:</b>				
Service cost	¥ 989	¥ 896	¥ 921	<b>\$10,514</b>
Interest cost	294	279	276	<b>3,128</b>
Expected return on plan assets	(208)	(198)	(195)	<b>(2,209)</b>
Recognized actuarial loss	309	182	169	<b>3,289</b>
Contribution to defined contribution pension plan	928	862	791	<b>9,865</b>
Net periodic benefit cost	¥2,312	¥2,021	¥1,962	<b>\$24,587</b>
<b>For directors:</b>				
Accrual for retirement benefit	¥ 52	¥ 69	¥ 38	<b>\$ 553</b>

Assumptions used in the accounting for retirement and severance benefits for the three years ended March 31, 2013 were as follows:

	2013	2012	2011
Method of attributing benefit to period of service	<b>Straight-line basis</b>	Straight-line basis	Straight-line basis
Discount rate	<b>mainly, 0.99%</b>	mainly, 2.00%	mainly, 2.00%
Expected return on plan assets	<b>mainly, 2.00%</b>	mainly, 2.00%	mainly, 2.00%
Amortization period for actuarial losses*	<b>mainly, 14 years</b>	mainly, 14 years	mainly, 14 years

\* Amortized on a straight-line basis over the average remaining service period for employees in service starting from the year in which the losses occur.

The domestic subsidiary and the overseas subsidiary have a lump-sum severance plan and adopted the permitted alternative treatment, accruing for 100% of the amount required if all employees were to voluntarily terminate their

employment as of the balance sheet date, in accordance with the accounting standard for retirement benefits for small business entities.

### 13. Net Assets

Under the Japanese laws and regulations, the entire amount paid for new shares is required to be designated as common stock. However, a company may, by a resolution of the Board of Directors, designate an amount not exceeding one-half of the price of the new shares as additional paid-in capital, which is included in capital surplus.

Under the Japanese Corporate Law ("The Law"), in cases where dividend distribution of surplus is made, the smaller of an amount equal to 10% of the dividend and the excess, if any, of 25% of common stock over the total of additional paid-in capital and legal earnings reserve must be set aside as additional paid-in capital or legal earnings reserve. Legal earnings reserve is included in retained earnings in the accompanying consolidated balance sheets and amounted to ¥1,551 million (\$16,496 thousand) and ¥1,551 million as of March 31, 2013 and 2012, respectively.

The Law also provides for companies to purchase treasury stock and to dispose and cancel of such treasury stock by resolution of the Board of Directors.

For the year ended March 31, 2013, the Company acquired shares of the Company's common stock under its

acquisition plan approved by the Company's Board of Directors on August 1, 2012. As a result, treasury shares increased by ¥13,739 million (\$146,077 thousand) for the year ended March 31, 2013.

For the year ended March 31, 2013, the Company canceled 4,938,500 shares on November 16, 2012 in accordance with board resolutions on November 1, 2012. As a result, capital surplus, retained earnings and treasury stock decreased by ¥660 million (\$7,015 thousand), ¥13,080 million (\$139,081 thousand) and ¥13,740 million (\$146,095 thousand), respectively.

As a result, treasury stock as of March 31, 2013 amounted to ¥2 million (\$27 thousand).

Cash dividends charged to retained earnings during the three years ended March 31, 2013, 2012 and 2011 represent dividends paid out during the periods. The accompanying consolidated financial statements do not include any provision for the year-end dividend of ¥50 (\$0.53) per share, aggregating ¥4,123 million (\$43,843 thousand) which was approved at the Company's shareholders' meeting on June 25, 2013 in respect of the year ended March 31, 2013.

### 14. Stock Options

The Company has stock-based compensation plans under which stock options are granted annually to directors and corporate officers at the market price on the date of the grant. The stock options granted before 2012 are fully exercisable after two years and expire ten years from the date of grant.

## Notes to Consolidated Financial Statements

Stock options existing as of March 31, 2013 were as follows:

Stock options granted	2012	2011	2010	2009
Persons granted	Directors and corporate officers: 10	Directors and corporate officers: 10	Directors and corporate officers: 10	Directors and corporate officers: 12
Number of shares	Common Stock 124,300	Common Stock 114,500	Common Stock 120,500	Common Stock 168,400
Date of grant	July 4, 2012	July 5, 2011	July 6, 2010	July 3, 2009
Vesting conditions	No provisions	No provisions	No provisions	No provisions
Service period	No provisions	No provisions	No provisions	No provisions
Exercise period	From June 23, 2014 to June 20, 2022	From June 24, 2013 to June 22, 2021	From June 25, 2012 to June 23, 2020	From June 27, 2011 to June 24, 2019

Stock options granted	2008	2007	2006	2005
Persons granted	Directors and corporate officers: 12	Directors and corporate officers: 12	Directors and corporate officers: 15	Directors and corporate officers: 15
Number of shares	Common Stock 161,700	Common Stock 99,300	Common Stock 102,700	Common Stock 129,200
Date of grant	July 2, 2008	July 3, 2007	July 4, 2006	July 4, 2005
Vesting conditions	No provisions	No provisions	No provisions	No provisions
Service period	No provisions	No provisions	No provisions	No provisions
Exercise period	From June 28, 2010 to June 25, 2018	From June 27, 2009 to June 26, 2017	From June 28, 2008 to June 24, 2016	From June 25, 2007 to June 23, 2015

Stock options granted	2004	2003	2002
Persons granted	Directors and corporate officers: 11	Directors and corporate officers: 12	Directors and corporate officers: 14
Number of shares	Common Stock 78,200	Common Stock 137,600	Common Stock 92,000
Date of grant	July 5, 2004	July 4, 2003	July 5, 2002
Vesting conditions	No provisions	No provisions	No provisions
Service period	No provisions	No provisions	No provisions
Exercise period	From June 26, 2006 to June 24, 2014	From June 27, 2005 to June 25, 2013	From June 27, 2004 to June 25, 2012

Number, movement and price of stock options for the year ended March 31, 2013 were as follows:

### Before vesting options (Number of shares):

Stock options granted	2012	2011	2010	2009	2008	2007
Balance at April 1, 2012	—	—	—	—	—	—
Granted	124,300	—	—	—	—	—
Vested	124,300	—	—	—	—	—
<b>Balance at March 31, 2013</b>	<b>—</b>	<b>—</b>	<b>—</b>	<b>—</b>	<b>—</b>	<b>—</b>

Stock options granted	2006	2005	2004	2003	2002
Balance at April 1, 2012	—	—	—	—	—
Granted	—	—	—	—	—
Vested	—	—	—	—	—
<b>Balance at March 31, 2013</b>	<b>—</b>	<b>—</b>	<b>—</b>	<b>—</b>	<b>—</b>

**After vesting options (Number of shares):**

Stock options granted	2012	2011	2010	2009	2008	2007
Balance at April 1, 2012	—	114,500	120,500	168,400	156,800	99,300
Vested	124,300	—	—	—	—	—
Exercised	—	—	28,800	57,600	52,800	9,800
<b>Balance at March 31, 2013</b>	<b>124,300</b>	<b>114,500</b>	<b>91,700</b>	<b>110,800</b>	<b>104,000</b>	<b>89,500</b>

Stock options granted	2006	2005	2004	2003
Balance at April 1, 2012	92,100	101,000	30,700	900
Vested	—	—	—	—
Exercised	21,300	62,100	28,400	—
<b>Balance at March 31, 2013</b>	<b>70,800</b>	<b>38,900</b>	<b>2,300</b>	<b>900</b>

**Price information (yen):**

Stock options granted	2012	2011	2010	2009	2008	2007
Option price	3,315	3,230	3,170	2,920	2,734	3,050
Weight-average stock price	—	—	3,838	3,616	3,531	4,270
Fair value at grant date	439.00	402.99	403.71	427.73	423.16	609.45

Stock options granted	2006	2005	2004	2003
Option price	2,715	2,480	1,743	1,176
Weight-average stock price	3,698	3,610	3,435	—
Fair value at grant date*	579.05	—	—	—

\* Omitted due to stock options which had been granted before the Law became effective on May 1, 2006.

On June 25, 2013, the Company's shareholders' meeting approved that the Company's stock subscription rights for allotment as stock options to directors and corporate officers of the Company. These stock subscription rights are exercisable from three years after allotment to ten years after allotment. The maximum number of stock subscription rights that can be exercised is 30,600 common shares.

## 15. Research and Development Expenditures

Research and development expenditures charged to income as incurred for the years ended March 31, 2013, 2012 and 2011 were ¥16,720 million (\$177,777 thousand), ¥17,225 and ¥13,221 million, respectively.

## 16. Income Taxes

The Company and its domestic subsidiary are subject to a number of taxes based on earnings which, in the aggregate, resulted in an average normal tax rate of approximately 37.9%, 40.4% and 40.4% for the three years ended March 31, 2013, respectively. Overseas subsidiaries are subject to income taxes of the countries in which they operate.

The reasons for the effective rates for the three years ended March 31, 2013, differ from the normal tax rates were as follows:

	2013	2012	2011
Normal tax rate	<b>37.9%</b>	40.4%	40.4%
Change in valuation allowance allocated to income tax expenses	<b>2.8</b>	(0.3)	(5.2)
Expenses not deductible for tax purposes	<b>1.5</b>	1.1	0.7
Lower tax rates of subsidiaries	<b>(0.5)</b>	0.3	(0.5)
Tax effect from change in tax rates by tax reform	<b>(0.5)</b>	2.7	—
Tax credit for research and development expenses	<b>(5.1)</b>	(6.2)	(4.3)
Others	<b>0.7</b>	0.2	0.2
<b>Effective tax rate</b>	<b>35.4%</b>	38.2%	31.3%

## Notes to Consolidated Financial Statements

The tax effects of temporary differences and tax loss carryforwards that gave rise to significant portions of the deferred tax assets and deferred tax liabilities at March 31, 2013 and 2012 were as follows:

	Millions of yen	Thousands of U.S. dollars	
	2013	2012	2013
<b>Deferred tax assets:</b>			
Tax loss carryforwards	¥ 5,842	¥ 5,605	\$ 62,112
Retirement and severance benefits	2,562	2,633	27,239
Depreciation and amortization	1,037	894	11,025
Accrued expenses	882	876	9,383
Advance payment	821	812	8,729
Deferred assets for tax purposes	626	1,279	6,658
Accrued enterprise taxes	321	418	3,416
Retirement and severance benefits for directors	88	79	939
Loss on impairment of golf membership rights	58	58	618
Loss on valuation of securities	57	57	604
Loss on valuation of inventories	43	30	462
Loss on impairment of fixed assets	18	18	187
Other	1,837	1,419	19,528
<b>Subtotal</b>	<b>14,192</b>	14,178	<b>150,900</b>
Valuation allowance	(6,764)	(5,683)	(71,916)
<b>Total gross deferred tax assets</b>	<b>7,428</b>	8,495	<b>78,984</b>
<b>Deferred tax liabilities:</b>			
In-process research and development	(2,256)	(1,980)	(23,984)
Net unrealized holding gains on securities	(1,057)	(30)	(11,242)
Reserve for special depreciation	(18)	(32)	(188)
Other	(26)	(28)	(278)
<b>Total gross deferred tax liabilities</b>	<b>(3,357)</b>	(2,070)	<b>(35,692)</b>
<b>Net deferred tax assets</b>	<b>¥ 4,071</b>	¥ 6,425	<b>\$ 43,292</b>

Net deferred tax assets at March 31, 2013 and 2012 were reflected in the accompanying consolidated balance sheets under the following captions:

	Millions of yen	Thousands of U.S. dollars	
	2013	2012	2013
<b>Current assets – deferred tax assets</b>			
Investments and other assets – deferred tax assets	¥ 1,880	¥ 1,921	\$ 19,995
<b>Non-current liabilities – deferred tax liabilities</b>	<b>4,460</b>	6,500	<b>47,425</b>
<b>Net deferred tax assets</b>	<b>(2,269)</b>	(1,996)	<b>(24,128)</b>
	¥ 4,071	¥ 6,425	\$ 43,292

### Adjustment of deferred tax assets and liabilities for enacted changes in tax laws and rates

According to the promulgation of the "Act for Partial Revision of the Income Tax Act, etc. for the Purpose of Creating Taxation System Responding to Changes in Economic and Social Structures" (Act No. 114 of 2011) and the "Act on Special Measures for Securing Financial Resources Neces-

sary to Implement Measures for Reconstruction Following the Great East Japan Earthquake" (Act No. 117 of 2011), effective from the fiscal year beginning on and after April 1, 2012, the corporate tax rate will be reduced and a special recovery tax will be imposed.

In accordance with this reform, the effective statutory tax rates which are used to calculate deferred tax assets and

deferred tax liabilities will be reduced to 37.9% from 40.4% for temporary differences expected to be reversed on or after April 1, 2012, and to 35.5% for temporary

differences expected to be recovered or settled on or after April 1, 2015.

## 17. Contingent Liabilities

The Company has provided guarantees to financial institutions covering employee loans. As of March 31, 2013, the total amount of outstanding guarantees was ¥130 million (\$1,380 thousand).

## 18. Segment Information

### General information about reportable segments

The determination of the Companies' operating segments is based on the organization units for which information is reported to the Company's chief operating decision making body, the Board of Directors. The Board of Directors reviews the internal report in order to assess performance and allocate resources. "Pharmaceuticals" is the Companies' only one reportable segment and includes manufacturing and distribution of prescription and OTC pharmaceuticals.

### Basis of measurement about reported segment profit or loss, segment assets, segment liabilities and other material items

The accounting policies for the reportable segments are basically the same as those described in Note 2, Summary of Significant Accounting Policies. Performance is measured based on segment operating profit. Transfer pricing between reportable segments are determined on an arm's length basis.

Information about reported segment profit (loss), segment assets, segment liabilities and other material items was as follows:

For the year ended March 31, 2013	Millions of yen				
	Pharmaceuticals	Other	Total	Adjustments	Consolidated
Net Sales:					
External customers	¥116,810	¥2,256	¥119,066	¥ —	¥119,066
Intersegment	—	114	114	(114)	—
Total	116,810	2,370	119,180	(114)	119,066
Segment profit (loss)	25,354	(673)	24,681	—	24,681
Segment assets	120,546	2,444	122,990	76,651	199,641
Other items:					
Depreciation and amortization	2,607	50	2,657	—	2,657
Amortization of goodwill	634	—	634	—	634
Increase in property, plant and equipment and intangible assets	5,198	45	5,243	—	5,243

For the year ended March 31, 2012	Millions of yen				
	Pharmaceuticals	Other	Total	Adjustments	Consolidated
Net Sales:					
External customers	¥111,846	¥2,570	¥114,416	¥ —	¥114,416
Intersegment	—	113	113	(113)	—
Total	111,846	2,683	114,529	(113)	114,416
Segment profit	26,684	48	26,732	—	26,732
Segment assets	106,535	2,126	108,661	90,140	198,801
Other items:					
Depreciation and amortization	2,718	69	2,787	—	2,787
Amortization of goodwill	162	—	162	—	162
Increase in property, plant and equipment and intangible assets	15,902	69	15,971	—	15,971

## Notes to Consolidated Financial Statements

For the year ended March 31, 2011	Millions of yen				
	Pharmaceuticals	Other	Total	Adjustments	Consolidated
<b>Net Sales:</b>					
External customers	¥108,576	¥2,236	¥110,812	¥ —	¥110,812
Intersegment	—	122	122	(122)	—
Total	108,576	2,358	110,934	(122)	110,812
Segment profit	30,518	221	30,739	—	30,739
Segment assets	90,067	1,814	91,881	92,920	184,801
<b>Other items:</b>					
Depreciation and amortization	2,901	75	2,976	—	2,976
Increase in property, plant and equipment and intangible assets	2,143	44	2,187	—	2,187
Thousands of U.S. dollars					
For the year ended March 31, 2013	Pharmaceuticals	Other	Total	Adjustments	Consolidated
	\$1,242,002	\$23,985	\$1,265,987	\$ —	\$1,265,987
<b>Net Sales:</b>					
External customers	\$1,242,002	\$23,985	\$1,265,987	\$ —	\$1,265,987
Intersegment	—	1,213	1,213	(1,213)	—
Total	1,242,002	25,198	1,267,200	(1,213)	1,265,987
Segment profit (loss)	269,583	(7,156)	262,427	—	262,427
Segment assets	1,281,722	25,985	1,307,707	815,000	2,122,707
<b>Other items:</b>					
Depreciation and amortization	27,713	534	28,247	—	28,247
Amortization of goodwill	6,744	—	6,744	—	6,744
Increase in property, plant and equipment and intangible assets	55,269	479	55,748	—	55,748

Notes: 1. "Other" mainly includes the medical device business segments.

2. "Segment profit" is reconciled for operating income described in the Consolidated Statements of Income and Comprehensive Income.

3. "Adjustments" represents unallocated corporate assets which principally include surplus operating capital (cash and cash equivalents, short-term investments and investment securities) and deferred tax assets.

4. "Depreciation and amortization" and "Increase in property, plant and equipment and intangible assets" include long-term prepaid expenses and its amortization.

Information about products and services was as follows:

	Millions of yen			Thousands of U.S. dollars
	2013	2012	2011	2013
Pharmaceuticals:				
Prescription pharmaceuticals:				
Ophthalmic	¥ 98,981	¥ 93,620	¥ 90,797	\$1,052,436
Anti-rheumatic pharmaceuticals	9,874	9,987	9,834	104,988
Other prescription pharmaceuticals	1,481	3,642	3,222	15,742
OTC pharmaceuticals	6,474	4,597	4,723	68,836
Other:				
Medical devices	2,246	2,558	2,225	23,874
Other	10	12	11	111
Total	¥119,066	¥114,416	¥110,812	\$1,265,987

Information about geographic areas was as follows:

	Millions of yen			Thousands of U.S. dollars
	2013	2012	2011	2013
Net Sales:				
Japan	¥100,712	¥ 95,374	¥ 92,549	\$1,070,826
Europe	9,202	8,880	8,517	97,845
North America	582	3,451	3,070	6,192
Asia	8,560	6,706	6,668	91,014
Other	10	5	8	110
Total	¥119,066	¥114,416	¥110,812	\$1,265,987
Property, plant and equipment:				
Japan	¥22,560	¥21,157	¥20,939	\$239,878
Europe	2,597	2,245	1,962	27,618
North America	710	635	478	7,545
Asia	1,553	1,486	1,578	16,508
Total	¥27,420	¥25,523	¥24,957	\$291,549

Information about major customers was as follows:

	Millions of yen			Thousands of U.S. dollars	Related business segment
	2013	2012	2011	2013	
Suzuken Co., Ltd.	¥25,486	¥23,297	¥21,465	\$270,978	Pharmaceuticals
Mediceo Corporation	21,716	20,392	20,712	230,902	Pharmaceuticals
Toho Pharmaceutical Co., Ltd.	11,929	11,825	11,567	126,839	Pharmaceuticals

Information about loss on impairment of fixed assets by reportable segment was as follows:

	Millions of yen			Thousands of U.S. dollars
	2013	2012	2011	2013
Pharmaceuticals	¥—	¥19	¥—	\$—
Other	—	—	—	—
Total	¥—	¥19	¥—	\$—

## Notes to Consolidated Financial Statements

Information about amortization of goodwill and unamortized balances by reportable segment was as follows:

	Millions of yen	Thousands of U.S. dollars	
	2013	2012	2013
<b>Amortization of goodwill:</b>			
Pharmaceuticals	¥634	¥162	<b>\$6,744</b>
Other	—	—	—
<b>Total</b>	<b>¥634</b>	¥162	<b>\$6,744</b>
 <b>Balance at end of period:</b>			
Pharmaceuticals	¥5,936	¥5,802	<b>\$63,118</b>
Other	—	—	—
<b>Total</b>	<b>¥5,936</b>	¥5,802	<b>\$63,118</b>

## 19. Subsequent Events

### Capital increase for a subsidiary

On April 26, 2013, the Company's Board of Directors made a resolution of capital increase for a subsidiary, Santen Holdings EU B.V. and executed.

#### 1. Purpose of the capital increase

To fulfill financial requirements in European operations

#### 2. Details of the Board resolution regarding the capital increase

Price: €30,000 thousand

Period: May, 2013

#### 3. Details of subsidiary

Name: Santen Holdings EU B.V.

Location: Amsterdam, Kingdom of the Netherlands

Representative: Masamichi Sato, President

Description of business: Holding company for European operations

Shareholder's equity: Before capital increase: €50 thousand (100% share)

After capital increase: €30,050 thousand (100% share)

# Internal Control Report

## 1 Framework of internal control over financial reporting

I, as President and CEO of Santen Pharmaceutical Co., Ltd. (the Company), am responsible for the design and operation of internal controls over financial reporting ("ICOFR") and establishing and maintaining an ICOFR based on the framework of ICOFR in Japan in accordance with "On the Setting of the Standards and Practice Standards for Management Assessment and Audit concerning Internal Control Over Financial Report (Business Accounting Council (Council Opinions), February 15, 2007)."

Internal control aims at achieving the objectives to a reasonable extent with the organized and integrated function of individual component as a whole. Therefore ICOFR does not provide an absolute assurance for preventing and detecting all errors to consolidated financial statements.

## 2 Assessment Scope, Timing and Procedures

### Basis of Presenting Internal Control Report

The report on ICOFR of the consolidated financial statements of the Company ("Internal Control Report") is prepared on the basis of generally accepted assessment standards of internal control over financial reporting in Japan ("Assessment Standards") and is compiled from the Internal Control Report prepared by the Company as required by the Financial Instruments and Exchange Law of Japan ("Law").

The Assessment Standards require management to assess ICOFR, which consists of the internal controls over the consolidated financial statements included in the Annual Securities Report filed under the Law and the internal control over disclosure information and others included in the Annual Securities Report that materially affects the reliability of the financial statements.

The scope of management's assessment of ICOFR in this annual report is different from the scope required by the Assessment Standards. Management assessment of ICOFR in this annual report covers the ICOFR with respect to the accompanying consolidated financial statements only. In addition, as explained in Note 1 on the basis of presentation of consolidated financial statements, the accompanying consolidated financial statements are reclassified and modified from the consolidated financial statements prepared for the purpose of the Law. Supplementary information is also added to the consolidated financial statements. The process of making reclassifications and modifications and the addition of certain information is for the convenience of readers outside Japan. Management voluntarily includes the process in its assessment of ICOFR, even though it is outside the scope of the Assessment Standards.

### Scope of Assessment

Management's assessment of ICOFR was conducted as of March 31, 2013 in accordance with the Assessment Standards.

In evaluating internal controls, management first assessed internal controls that have a material impact on overall consolidated financial reporting ("company-level controls") and, based on the results, selected business process to be assessed. For assessment of process level controls management analyzed the selected business processes, identify a key control that would have a material impact on the reliability of financial reporting, and assessed effectiveness of internal controls through assessing design and operation of the key controls.

Management assessed the effectiveness of the ICOFR applicable for the Company and its subsidiaries, to extent necessary in light of their degree of impact on the reliability of financial reporting. Management determined materiality for reliability of financial reporting in light of their degree of quantitative and qualitative impact on financial reporting. From the results of the company-level controls assessment of the Company and two subsidiaries, management determined a reasonable scope for process level controls to be assessed.

Management selected the Pharmaceuticals business unit of the Company as the significant business unit for assessing process level controls, as its sales was more than 80% of the previous fiscal year's consolidated net sales. The process related to net sales, account receivables and inventories from the Pharmaceuticals business unit of the Company was selected for process level control assessment as they have significant relation to the business objectives of the Company. Apart from selected significant business units, including other business units, processes whose accounts were determined to have a high risk of misstatement and involves significant use of management estimate and projection, and processes whose businesses or operations included high risk transactions were additionally selected for controls assessment.

## 3 Results of assessment

Based on our assessment procedures noted above, I concluded the Company's internal control over financial reporting was effective as of March 31, 2013.

## 4 Supplementary information

No subsequent events have arisen that has caused to materially effect our evaluation of the effectiveness on the internal control over financial reporting as of March 31, 2013.

## 5 Other

None.



Akira Kurokawa  
President & CEO

August 9, 2013

# Independent Auditor's Report



To the Board of Directors of  
Santen Pharmaceutical Co., Ltd.:

## **Report on the Consolidated Financial Statements**

We have audited the accompanying consolidated financial statements of Santen Pharmaceutical Co., Ltd. and its consolidated subsidiaries, which comprise the consolidated balance sheets as at March 31, 2013 and 2012, and the consolidated statements of income and comprehensive income, statements of changes in net assets and statements of cash flows for each of the three-year in the period ended March 31, 2013, and a summary of significant accounting policies and other explanatory information.

### **Management's Responsibility for the Consolidated Financial Statements**

Management is responsible for the preparation and fair presentation of these consolidated financial statements in accordance with accounting principles generally accepted in Japan, and for such internal control as management determines is necessary to enable the preparation of consolidated financial statements that are free from material misstatements, whether due to fraud or error.

### **Auditor's Responsibility**

Our responsibility is to express an opinion on these consolidated financial statements based on our audits. We conducted our audits in accordance with auditing standards generally accepted in Japan. Those standards require that we comply with ethical requirements and plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free from material misstatement.

An audit involves performing procedures to obtain audit evidence about the amounts and disclosures in the consolidated financial statements. The procedures selected depend on our judgement, including the assessment of the risks of material misstatement of the consolidated financial statements, whether due to fraud or error. In making those risk assessments, we consider internal control relevant to the entity's preparation and fair presentation of the consolidated financial statements in order to design audit procedures that are appropriate in the circumstances, while the objective of the financial statement audit is not for the purpose of expressing an opinion on the effectiveness of the entity's internal control. An audit also includes evaluating the appropriateness of accounting policies used and the reasonableness of accounting estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our audit opinion.

### **Opinion**

In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of Santen Pharmaceutical Co., Ltd. and its consolidated subsidiaries as at March 31, 2013 and 2012, and their financial performance and cash flows for each of the three-year in the period ended March 31, 2013, in accordance with accounting principles generally accepted in Japan.

### **Convenience Translation**

The U.S. dollar amounts in the accompanying consolidated financial statements with respect to the year ended March 31, 2013 are presented solely for convenience. Our audit also included the translation of yen amounts into U.S. dollar amounts and, in our opinion, such translation has been made on the basis described in Note 3, to the consolidated financial statements.

## **Report on the Internal Control Report**

We also have audited the accompanying report on internal control over financial reporting of the consolidated financial statements of Santen Pharmaceutical Co., Ltd. as at March 31, 2013 ("Internal Control Report").

### **Management's Responsibility for the Internal Control Report**

Management is responsible for the design and operation of internal control over financial reporting and the preparation and fair presentation of the internal control report in conformity with assessment standards for internal control over financial reporting generally accepted in Japan. Internal control over financial reporting may not completely prevent or detect financial statement misstatements.

### **Auditor's Responsibility**

Our responsibility is to express an opinion on the internal control report based on our internal control audit. We conducted our internal control audit in accordance with auditing standards for internal control over financial reporting generally accepted in Japan. Those standards require that we comply with ethical requirements and plan and perform the audit to obtain reasonable assurance about whether the Internal Control Report is free from material misstatement.

An internal control audit involves performing procedures to obtain audit evidence about the assessment of internal control over financial reporting in the Internal Control Report. The procedures selected depend on the auditor's judgement, including significance of effect on the reliability of financial reporting. Also, an internal control audit includes evaluating the appropriateness of the scope, procedures and result of the assessment determined and presented by management, and the overall internal control report presentation. We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

### **Opinion**

In our opinion, the Internal Control Report, in which Santen Pharmaceutical Co., Ltd. states that internal control over financial reporting was effective as at March 31, 2013, presents fairly, in all material respects, the assessment of internal control over financial reporting in conformity with assessment standards for internal control over financial reporting generally accepted in Japan.

KPMG AZSA LLC

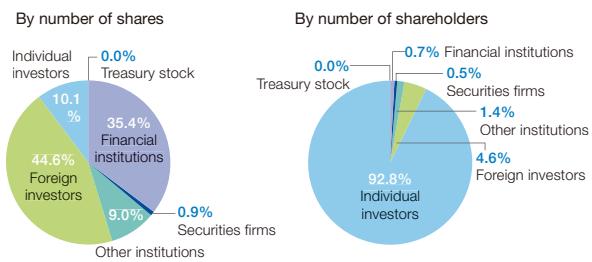
August 9, 2013  
Osaka, Japan

# Corporate Information / Stock Information

As of March 31, 2013

Corporate Headquarters	Santen Pharmaceutical Co., Ltd. Grand Front Osaka Tower A, 4-20 Ofuka-cho, Kita-ku, Osaka 530-8552, Japan (Reception desk is on the 25th Floor.) * Some head office functions were relocated on June 17, 2013. URL: <a href="http://www.santen.com">http://www.santen.com</a> Investor relations contact: TEL: +81-6-6321-7000 (Main) +81-6-4802-9360 (IR) E-MAIL: <a href="mailto:ir@santen.co.jp">ir@santen.co.jp</a>
Established	1890
Paid-in Capital	¥7,081 million
Number of Shareholders	7,998
Stock Exchange Listings	Tokyo and Osaka * The cash equity markets of the Tokyo Stock Exchange and the Osaka Securities Exchange were integrated in July 2013.
Ticker Code	4536
Transfer Agent	Mitsubishi UFJ Trust and Banking Corporation 6-3, Fushimi-cho 3-chome, Chuo-ku, Osaka 541-8502, Japan
Major Offices	Sendai, Tokyo, Nagoya, Osaka and Fukuoka
Manufacturing Plants	Noto and Shiga
Research Laboratory	Nara Research and Development Center
Number of Employees	3,050 (non-consolidated: 1,903)
Number of Shares Issued	82,469,103

## Composition of Shareholders

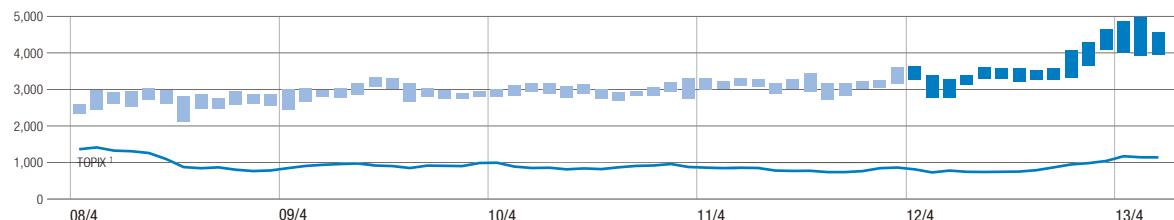


## Major Shareholders

Name	Number of shares held	Percentage of investment
Japan Trustee Service Bank, Ltd.	10,186 Thousand shares	12.4%
State Street Bank and Trust Company	505223	5.8
Development Bank of Japan Inc.	3,310	4.0
The Master Trust Bank of Japan, Ltd.	2,978	3.6
Nippon Life Insurance Company	2,696	3.3
The Bank of Tokyo-Mitsubishi UFJ, Ltd.	2,120	2.6
State Street Bank and Trust Company	2,052	2.5
RBC IST London-Lending Account	1,965	2.4
The Chase Manhattan Bank, N.A. London Secs Lending Omnibus Account	1,929	2.3
Daiichi Sankyo Company, Ltd.	1,836	2.2

## Stock Price Range (Yen)

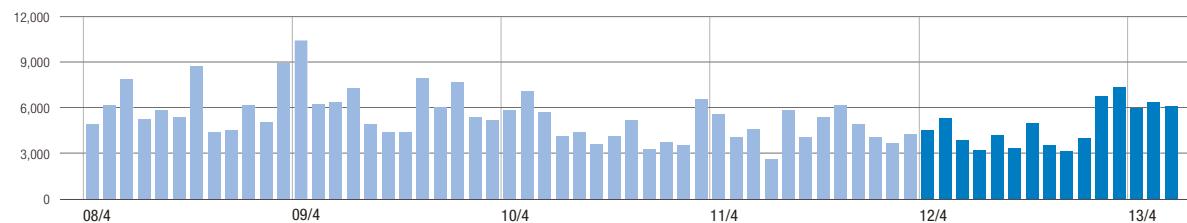
Osaka Securities Exchange (monthly basis)



1. TOPIX: Tokyo stock price index

## Trading Volume (Thousands of shares)

Osaka Securities Exchange (monthly basis)



## Yearly High and Low Prices

	2009	2010	2011	2012	2013
High (yen)	3,340	3,195	3,445	3,655	4,990
Low (yen)	2,460	2,694	2,731	2,778	3,330

Note: Calendar years. Stock prices for 2013 are for the period to the end of June.

# Business Bases

As of August 2013



## Plants and Laboratory



### ① Noto Plant

2-14, Shikinami, Houdatsushimizu-cho,  
Hakui-gun, Ishikawa 929-1494, Japan  
TEL: +81-767-29-2666 FAX: +81-767-29-4233



### ② Shiga Product Supply Center

348-3, Aza-suwa, Oaza-shide, Taga-cho,  
Inukami-gun, Shiga 522-0314, Japan  
TEL: +81-749-48-2900 FAX: +81-749-48-2901



### ③ Tampere Plant

Niittyhaankatu 20, P.O. Box 33,  
FIN-33721 Tampere, Finland  
TEL: +358-3-284-8111 FAX: +358-3-318-1900



### ④ Suzhou Plant

No. 169 Tinglan Road, Suzhou Industrial Park,  
Jiangsu Province 215026, P.R.C.  
TEL: +86-512-6295-7500 FAX: +86-512-6295-7800



### ⑤ Nara Research and Development Center

8916-16, Takayama-cho, Ikoma-shi, Nara  
630-0101, Japan  
TEL: +81-743-79-4501 FAX: +81-743-79-4521

Corporate Headquarters and Subsidiaries		
		Business
① Corporate Headquarters	Grand Front Osaka Tower A, 4-20 Ofuka-cho, Kita-ku, Osaka 530-8552, Japan (Reception desk is on the 25th Floor.) TEL: +81-6-6321-7000 FAX: +81-6-6328-5082	Research, development, production, marketing of pharmaceuticals and medical devices
② Claire Co., Ltd	348-3, Aza-suwa, Oaza-shide, Taga-cho, Inukami-gun, Shiga 522-0314, Japan TEL: +81-749-48-2234 FAX: +81-749-48-2239	Cleaning of antidust and sterilized clothing
③ Santen Holdings U.S. Inc.	2100 Powell Street, Suite 1600, Emeryville, California 94608, U.S.A.	Holding company for North American businesses and business development
④ Santen Inc.	2100 Powell Street, Suite 1600, Emeryville, California 94608, U.S.A. TEL: +1-415-268-9100 FAX: +1-510-655-5682	Clinical development of pharmaceuticals and business development
⑤ Advanced Vision Science, Inc.	5743 Thornwood Drive, Goleta, California 93117, U.S.A. TEL: +1-805-683-3851 FAX: +1-805-964-3065	Development, production, marketing of medical devices
⑥ Santen Holdings EU B.V.	Herikerbergweg 238, 1101CM Amsterdam Zuidoost, Netherlands	Centralization of financial controls for European operations
⑦ Santen Oy	Niittyhaankatu 20, P.O. Box 33, FIN-33721 Tampere, Finland TEL: +358-3-284-8111 FAX: +358-3-318-1900	Research, development, production, marketing of pharmaceuticals
⑧ Santen S.A.S.	1 rue Pierre Fontaine, Genavenir IV, F-91058 Evry cedex, France TEL: +33-1-69-87-40-20 FAX: +33-1-69-87-40-30	Research, development, marketing of pharmaceuticals and medical devices
⑨ Santen GmbH	Erika-Mann-Strasse 21 80636 Munchen, Germany TEL: +49-89-848078-0 FAX: +49-89-848078-60	Business development, product planning, marketing of pharmaceuticals
⑩ SantenPharma AB	Solna torg 3, SE-17145 Solna, Sweden TEL: +46-8-83-4140 FAX: +46-8-83-4145	Marketing support of pharmaceuticals
⑪ Santen Pharmaceutical (China) Co., Ltd.	No. 169 Tinglan Road, Suzhou Industrial Park, Jiangsu Province 215026, P.R.C. TEL: +86-512-6295-7500 FAX: +86-512-6295-7800	Production, marketing, clinical development of pharmaceuticals
⑫ Santen Pharmaceutical Korea Co., Ltd.	3F C&K Tower, 35, Yeoksam-ro 25-gil, Gangnam-gu, Seoul, 135-921, Korea TEL: +82-2-754-1434 FAX: +82-2-754-2929	Marketing, clinical development of pharmaceuticals
⑬ Taiwan Santen Pharmaceutical Co., Ltd.	16F, No. 57, Sec. 2, Tun-Hwa South Rd., Taipei, R.O.C. TEL: +886-2-2700-1553 FAX: +886-2-2700-1730	Marketing of pharmaceuticals
⑭ Santen India Private Limited	No. 216, Raheja Chambers, 12 Museum Road, Bangalore 560 001, India TEL: +91-80-4932-3700 FAX: +91-80-4932-3799	Pharmaceutical market research
Other Office		
⑮ Beijing Representative Office	Suit 1206B, TOWER W3, Oriental Plaza, No. 1, East Chang An Ave., Dong Cheng District, Beijing 100738, P.R.C. TEL: +86-10-8515-1515 FAX: +86-10-8515-1020	

# History

## Company History

### 1890

Founder Kenkichi Taguchi opens Taguchi Santendo in Kitahama, Osaka

### 1925

Operations incorporated as Santendo Co., Ltd.

### 1935

Yodogawa Plant established in Higashiyodogawa-ku, Osaka

### 1944

Head Office transferred to Yodogawa Plant (Higashiyodogawa-ku, Osaka)

### 1945

Company name changed to Santendo Pharmaceutical Co., Ltd.

### 1958

Company name changed to current form of Santen Pharmaceutical Co., Ltd.

Santen enters prescription pharmaceutical business

### 1977

Stock listed on First Section of Tokyo Stock Exchange and Osaka Securities Exchange

Production system introduced to allow filling of solution into molded containers to make bottle-packed eye drops

### 1982

Central Research Laboratories established

### 1985

Noto Plant established

### 1990

Long-term business vision formulated to mark centenary

### 1993

Subsidiary Santen Inc. established in the U.S.

### 1994

Subsidiary Santen GmbH established in Germany

### 1996

Representative office established in Beijing, China  
Nara Research and Development Center and Shiga Plant (currently Shiga Product Supply Center) established

### 1997

Finnish ophthalmics pharmaceutical company acquired and Santen Oy established

Subsidiary Taiwan Santen Pharmaceutical Co., Ltd. established

### 1998

Medium-term Plan "Hitomi 21" formulated

### 2000

Subsidiary Santen Pharmaceutical Korea Co., Ltd. established

Representative office established in Guangzhou, China

### 2001

U.S.-based Advanced Vision Science, Inc. acquired

## 1900

### 1890s

Launch of *Heburin-gan*, a cold medicine



### 1899

Launch of *Daigaku Eye Drops*



### 1952

Launch of *Daigaku Penicillin Eye Drops*

### 1953

Launch of *Daigaku Mycillin Eye Drops*

### 1954

Launch of *Daigaku Super Eye Drops*

### 1962

Launch of *Mydrin-P*, a mydriatic drug (for pupil dilation)



Launch of *Super Sante* marks first use of plastic eye drop containers in Japan



### 1963

Launch of *Thiola*, an original liver detoxification agent



### 1965

Launch of *Sante de U*



## 1990

### 1970

Launch of antibiotic ophthalmic *Ecolicin*

### 1975

Launch of anti-inflammatory ophthalmic *Flumetholon*

### 1978

Santen commences sales of medical devices

### 1981

Launch of *Timoptol*, a treatment for glaucoma and ocular hypertension



### 1985

Launch of *Sante 40 NE*



### 1986

Santen commences sales of intraocular lenses



### 1987

Launch of anti-rheumatic *Rimatil*



Launch of anti-infective ophthalmic *Tarivid*



## 2000

### 1991

Launch of *Sante FX*

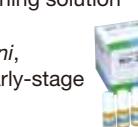


### 1992

Launch of *BSS PLUS*, an ophthalmic perfusion and bathing solution



Launch of *Kary Uni*, a treatment for early-stage senile cataracts



### 1995

Launch of *Hyalein*, a treatment for corneal and conjunctival epithelial disorders



Launch of anti-allergy ophthalmic *Alegysal*

Launch of anti-rheumatic *Azulfidine EN*



Launch of *Opegan Hi*, an adjuvant for ophthalmic operations



## Product History

Note: Based on the years when sales were launched by Santen Pharmaceutical.

<b>2002</b>	Introduced Dimple Bottle, an innovative patient-oriented container for ophthalmic solutions	<b>2006</b>	2006-2010 Medium-Term Management Plan formulated	<b>2010</b>	Santen Pharmaceutical Korea Co., Ltd. commenced direct marketing
<b>2003</b>	2003-2005 Medium-Term Management Plan formulated  ISO 14001 certification acquired by Noto Plant	<b>2007</b>	Representative office established in Shenyang, China  Santen Pharmaceutical (China) Co., Ltd. established Suzhou Plant	<b>2011</b>	2011-2013 Medium-Term Management Plan formulated
	Santen Activity Improved Navigator (SAIN) medical information support system developed	<b>2008</b>	Completion of pharmaceutical development building and ancillary building at Nara Research and Development Center	<b>2012</b>	Subsidiary Santen India Private Limited established in India
<b>2004</b>	U.S. sales partnership with Johnson & Johnson Vision Care, Inc. (currently VISTAKON Pharmaceuticals, LLC) started	<b>2009</b>	Santen Pharmaceutical (China) Co., Ltd. commenced direct marketing	<b>2013</b>	Acquired Novagali Pharma S.A.S. (currently Santen S.A.S.) and made it a wholly owned subsidiary
<b>2005</b>	Representative office established in Shanghai, China  Subsidiary Santen Pharmaceutical (China) Co., Ltd. established				Established Santen Holdings EU B.V. as a holding company
					Started integrated production at the Suzhou Plant
					Head Office transferred to Kita-ku, Osaka

## 2010

<b>1999</b>	Launch of <i>Timoptol XE</i> , a treatment for glaucoma and ocular hypertension  Launch of <i>Sante FX Neo</i>	<b>2004</b>	Launch of <i>Rescula</i> , a treatment for glaucoma and ocular hypertension  Launch of anti-rheumatic <i>Metolate</i>	<b>2009</b>	Launch of <i>Sante FX V Plus</i>  Launch of <i>Eternity Natural</i> foldable intraocular lens
<b>2000</b>	Launch of anti-infective ophthalmic <i>Cravit</i>	<b>2006</b>	Launch of <i>Papilock Mini</i> , a treatment for vernal keratoconjunctivitis  Launch of <i>Sante Medical 10</i>  Launch of <i>Sante AL Cool II</i>	<b>2010</b>	Launch of <i>Cosopt</i> , a treatment for glaucoma and ocular hypertension  Launch of <i>Diquas</i> , a treatment for dry eye
<b>2001</b>	Launch of <i>Detantol</i> , a treatment for glaucoma and ocular hypertension	<b>2007</b>	Launch of <i>Sante Uruoi Contact a</i>	<b>2012</b>	Launch of <i>Sante Medical Guard</i>  Launch of Intravitreal VEGF Inhibitor <i>EYLEA</i>  Launch of <i>Sante 40</i> series
	Launch of anti-allergy ophthalmic <i>Livostin</i>	<b>2008</b>	Launch of nutritional supplement <i>Sante Lutax</i>  Launch of <i>Sante 40i</i>  Launch of <i>Eternity</i> foldable intraocular lens	<b>2013</b>	Launch of <i>Eternity Natural Uni</i>  Launch of <i>Sante Beautéye</i>  Launch of <i>Sante PC</i>
<b>2002</b>	Launch of <i>Sante de U Plus E Alpha</i> Launch of <i>Sante 40</i>		Launch of <i>Tapros</i> , a treatment for glaucoma and ocular hypertension		
<b>2003</b>	Launch of <i>ClariFlex</i> foldable intraocular lenses				



[www.santen.com](http://www.santen.com)

The following are registered trademarks of Santen's alliance partners:  
*Cravit*, *Tarivid* and *Oftaquix* (Daiichi Sankyo Company, Limited); *Azulfidine* (Pfizer Inc.);  
*Alegysal* (Mitsubishi Tanabe Pharma Corporation); *Detantol* (Eisai Co., Ltd.);  
*Timoptol* and *Cosopt* (Merck & Co., Inc.); *Livostin* (Johnson & Johnson);  
*Rescula* (R-Tech Ueno, Ltd.); and *EYLEA* (Bayer AG).



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